

# Il-Ġurnal Uffiċjali tal-Unjoni Ewropea

C 285



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Informazzjoni u Avviżi

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Werrej

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INFORMAZZJONI MINN ISTITUZZJONIJET, KORPI, UFFIĊĠI U AĠENZJI TAL-UNJONI EWROPEA

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## IV

*(Informazzjoni)*INFORMAZZJONI MINN ISTITUZZJONIJIET, KORPI, UFFIĊĊJI U AĠENZIIJI TAL-  
UNJONI EWROPEA

## IL-KUMMISSJONI EWROPEA

**Sommarju ta' deċiżjonijiet tal-Unjoni Ewropea dwar l-awtorizzazzjonijiet għat-tqeghid fis-suq tal-  
prodotti mediċinali mill-1 ta' Lulju 2015 sal-31 ta' Lulju 2015***(Ippubblikat skont l-Artikolu 13 jew l-Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-  
Kunsill <sup>(1)</sup>)*

(2015/C 285/01)

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<sup>(1)</sup> ĠU L 136, 30.4.2004, p. 1.

— **Irriġ ta' awtorizzazzjoni għat-tqeghid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | INN (Denominazzjoni Internazzjonali Komuni) | Detentur tal-awtorizzazzjoni għat-tqeghid fis-suq                                                            | Numru tal-entrata fir-Reġistru Komunitarju | Forma farmaċewtika                                         | Kodiċi ATC (Kodiċi Anatomiku Terapewtiku Kimiku) | Data ta' notifiċa |
|--------------------|-----------------------------|---------------------------------------------|--------------------------------------------------------------------------------------------------------------|--------------------------------------------|------------------------------------------------------------|--------------------------------------------------|-------------------|
| 3.7.2015           | Hetlioz                     | tasimelteon                                 | Vanda Pharmaceuticals Limited<br>222 Regent Street, London W1B 5TR, United Kingdom                           | EU/1/15/1008                               | Kapsula, iebsa                                             | N05CH03                                          | 7.7.2015          |
| 13.7.2015          | EVOTAZ                      | atazanavir/cobicistat                       | Bristol-Myers Squibb Pharma EEIG<br>Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/15/1025                               | Pillola miksiġa b'rita                                     | J05AR15                                          | 15.7.2015         |
| 17.7.2015          | KEYTRUDA                    | pembrolizumab                               | Merck Sharp & Dohme Limited<br>Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom              | EU/1/15/1024                               | Trab għal konċentrat għal soluzzjoni għall-infużjoni       | L01XC18                                          | 21.7.2015         |
| 17.7.2015          | Pregabalin Zentiva          | pregabalin                                  | Zentiva, k.s.<br>U Kabelovny 130, 102 37 Praha 10, Česká republika                                           | EU/1/15/1021                               | Kapsula, iebsa                                             | N03AX16                                          | 21.7.2015         |
| 17.7.2015          | Repatha                     | evolocumab                                  | Amgen Europe B.V.<br>Minervum 7061, NL-4817 ZK Breda, Nederland                                              | EU/1/15/1016                               | Soluzzjoni għall-injezzjoni f'siringa mimlija għal-test    | C10AX13                                          | 21.7.2015         |
| 20.7.2015          | Bortezomib Accord           | bortezomib                                  | Accord Healthcare Limited<br>Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom   | EU/1/15/1019                               | Trab għal soluzzjoni għall-injezzjoni                      | L01XX32                                          | 23.7.2015         |
| 20.7.2015          | Nivolumab BMS               | nivolumab                                   | Bristol-Myers Squibb Pharma EEIG<br>Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom | EU/1/15/1026                               | Konċentrat għal soluzzjoni għal infużjoni                  | L01XC17                                          | 23.7.2015         |
| 28.7.2015          | Omidria                     | fenilefrina/ketorolak                       | Omeros London Limited<br>Berkeley Square, London, W1J 6BD, United Kingdom                                    | EU/1/15/1018                               | Konċentrat għal soluzzjoni għal irri-gazzjoni intraokulari | Pending                                          | 30.7.2015         |

— **Hruġ ta' awtorizzazzjoni għat-tqeghid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Miċhud**

| Data tad-deċiżjoni | Isem tal-prodott med-<br>icinali | Detentur tal-awtorizzazzjoni għat-tqeghid fis-suq                                                        | Numru tal-entrata fir-Re-<br>gistru Komunitarju | Data ta' noti-<br>fika |
|--------------------|----------------------------------|----------------------------------------------------------------------------------------------------------|-------------------------------------------------|------------------------|
| 3.7.2015           | Lympreva                         | Biovest Europe Limited<br>Evershed House, 70 Great Bridgewater St.,<br>Manchester M1 5ES, United Kingdom | —                                               | 7.7.2015               |

— **Modifika ta' awtorizzazzjoni għat-tqeghid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

| Data tad-deċiżjoni | Isem tal-prodott med-<br>icinali | Detentur tal-awtorizzazzjoni għat-tqeghid fis-suq                                                                   | Numru tal-entrata fir-Re-<br>gistru Komunitarju | Data ta' noti-<br>fika |
|--------------------|----------------------------------|---------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|------------------------|
| 3.7.2015           | ADCETRIS                         | Takeda Pharma A/S<br>Dybendal Alle 10, 2630 Taastrup, Danmark                                                       | EU/1/12/794                                     | 7.7.2015               |
| 3.7.2015           | Bemfol                           | FINOX Biotech AG<br>Gewerbstrasse 7, FL-9496 Balzers, Liechtenstein                                                 | EU/1/13/909                                     | 8.7.2015               |
| 3.7.2015           | Competact                        | Takeda Pharma A/S<br>Dybendal Alle 10, 2630 Taastrup, Danmark                                                       | EU/1/06/354                                     | 7.7.2015               |
| 3.7.2015           | Docetaxel Accord                 | Accord Healthcare Limited<br>Sage House, 319 Pinner Road, North Harrow,<br>Middlesex, HA1 4HF, United Kingdom       | EU/1/12/769                                     | 7.7.2015               |
| 3.7.2015           | Docetaxel Kabi                   | Fresenius Kabi Oncology Plc.<br>Lion Court, Farnham Road, Bordon, Hampshire<br>GU35 0NF, United Kingdom             | EU/1/12/770                                     | 7.7.2015               |
| 3.7.2015           | Fampyra                          | Biogen Idec Limited<br>Innovation House, 70 Norden Road, Maiden-<br>head, Berkshire SL6 4AY, United Kingdom         | EU/1/11/699                                     | 7.7.2015               |
| 3.7.2015           | GILENYA                          | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR,<br>United Kingdom                          | EU/1/11/677                                     | 7.7.2015               |
| 3.7.2015           | Hemangirol                       | Pierre Fabre Dermatologie<br>45 place Abel Gance, F- 92100 Boulogne, France                                         | EU/1/14/919                                     | 7.7.2015               |
| 3.7.2015           | IMBRUVICA                        | Janssen-Cilag International NV<br>Turnhoutseweg 30, B-2340 Beerse, België                                           | EU/1/14/945                                     | 7.7.2015               |
| 3.7.2015           | Neuraceq                         | Piramal Imaging Limited<br>Langstone Technology Park, Langstone Road,<br>Havant, Hampshire, PO9 1SA, United Kingdom | EU/1/13/906                                     | 7.7.2015               |

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur tal-awtorizzazzjoni għat-tqeghid fis-suq                                                     | Numru tal-entrata fir-Reġistru Komunitarju | Data ta' notifikazzjoni |
|--------------------|-----------------------------|-------------------------------------------------------------------------------------------------------|--------------------------------------------|-------------------------|
| 3.7.2015           | Pradaxa                     | Boehringer Ingelheim International GmbH<br>Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland | EU/1/08/442                                | 7.7.2015                |
| 3.7.2015           | Viramune                    | Boehringer Ingelheim International GmbH<br>Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland | EU/1/97/055                                | 7.7.2015                |
| 3.7.2015           | Zoledronic acid<br>medac    | medac Gesellschaft für klinische Spezialpräparate mbH<br>Theaterstr. 6, D-22880 Wedel, Deutschland    | EU/1/12/779                                | 7.7.2015                |
| 3.7.2015           | Zometa                      | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR, United Kingdom               | EU/1/01/176                                | 7.7.2015                |
| 8.7.2015           | Ambirix                     | GlaxoSmithKline Biologicals S.A.<br>rue de l'Institut 89, 1330 Rixensart, Belgique                    | EU/1/02/224                                | 10.7.2015               |
| 8.7.2015           | CONTROLOC Control           | Takeda GmbH, (HRB 701016)<br>Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland                         | EU/1/09/515                                | 10.7.2015               |
| 8.7.2015           | DuoResp Spiromax            | Teva Pharma B.V.<br>Computerweg 10, NL-3542 DR Utrecht, Nederland                                     | EU/1/14/920                                | 13.7.2015               |
| 8.7.2015           | Flebogamma DIF              | Instituto Grifols, S.A.<br>Can Guasch 2, Parets del Vallès, E-08150 Barcelona, España                 | EU/1/07/404                                | 10.7.2015               |
| 8.7.2015           | Foscan                      | biolitec pharma ltd.<br>Unit 9 A, Plato Business Park, Damastown, Dublin 15, Ireland.                 | EU/1/01/197                                | 10.7.2015               |
| 8.7.2015           | Iasibon                     | Pharmathen S.A.<br>6 Dervenakion, 15351 Pallini Attiki, Ελλάδα                                        | EU/1/10/659                                | 10.7.2015               |
| 8.7.2015           | Mimpara                     | Amgen Europe B.V.<br>Minervum 7061, NL-4817 ZK Breda, Nederland                                       | EU/1/04/292                                | 10.7.2015               |
| 8.7.2015           | PANTECTA Control            | Takeda GmbH, (HRB 701016)<br>Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland                         | EU/1/09/518                                | 10.7.2015               |
| 8.7.2015           | PANTOLOC Control            | Takeda GmbH, (HRB 701016)<br>Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland                         | EU/1/09/519                                | 10.7.2015               |
| 8.7.2015           | PANTOZOL Control            | Takeda GmbH, (HRB 701016)<br>Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland                         | EU/1/09/517                                | 10.7.2015               |

| Data tad-deċiżjoni | Isem tal-prodott mediċinali      | Detentur tal-awtorizzazzjoni għat-tqeghid fis-suq                                                                            | Numru tal-entrata fir-Reġistru Komunitarju | Data ta' notifiċa |
|--------------------|----------------------------------|------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|-------------------|
| 8.7.2015           | Perjeta                          | Roche Registration Limited<br>6 Falcon Way, Shire Park, Welwyn Garden City,<br>AL7 1TW, United Kingdom                       | EU/1/13/813                                | 10.7.2015         |
| 8.7.2015           | Pregabalin Pfizer                | Pfizer Limited<br>Ramsgate Road, Sandwich, Kent CT13 9NJ,<br>United Kingdom                                                  | EU/1/14/916                                | 10.7.2015         |
| 8.7.2015           | Ranexa                           | Menarini International Operations Lussemburgu S.A.<br>1 avenue de la Gare, L-1611 Lussemburgu,<br>Grand-Duché de Lussemburgu | EU/1/08/462                                | 10.7.2015         |
| 8.7.2015           | Remicade                         | Janssen Biologics B.V.<br>Einsteinweg 101, NL-2333 CB Leiden, Nederland                                                      | EU/1/99/116                                | 10.7.2015         |
| 8.7.2015           | SOMAC Control                    | Takeda GmbH, (HRB 701016)<br>Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland                                                | EU/1/09/516                                | 10.7.2015         |
| 8.7.2015           | Tandemact                        | Takeda Pharma A/S<br>Dybendal Alle 10, 2630 Taastrup, Danmark                                                                | EU/1/06/366                                | 10.7.2015         |
| 8.7.2015           | Vaniqa                           | Almirall, S.A.<br>Ronda General Mitre, 151, E-08022 Barcelona,<br>España                                                     | EU/1/01/173                                | 10.7.2015         |
| 8.7.2015           | Vimizim                          | BioMarin Europe Ltd<br>164 Shaftesbury Avenue, London WC2H 8HL,<br>United Kingdom                                            | EU/1/14/914                                | 10.7.2015         |
| 8.7.2015           | Yttriga                          | Eckert & Ziegler Radiopharma GmbH<br>Robert-Rössle-Str. 10, D-13125 Berlin, Deutschland                                      | EU/1/05/322                                | 10.7.2015         |
| 13.7.2015          | Xgeva                            | Amgen Europe B.V.<br>Minervum 7061, NL-4817 ZK Breda, Nederland                                                              | EU/1/11/703                                | 15.7.2015         |
| 13.7.2015          | Zoledronic acid<br>Teva Generics | Teva B.V.<br>Swensweg 5, 2031 GA Haarlem, Nederland                                                                          | EU/1/14/912                                | 15.7.2015         |
| 17.7.2015          | Aflunov                          | Novartis Vaccines Influenza S.r.l.<br>Via Fiorentina, 1, 53100 Siena, Italia                                                 | EU/1/10/658                                | 22.7.2015         |
| 17.7.2015          | Brilique                         | AstraZeneca AB<br>SE-151 85 Södertälje, Sverige                                                                              | EU/1/10/655                                | 21.7.2015         |
| 17.7.2015          | Circadin                         | RAD Neurim Pharmaceuticals EEC Limited<br>One Forbury Square, The Forbury, Reading,<br>Berkshire RG1 3EB, United Kingdom     | EU/1/07/392                                | 21.7.2015         |
| 17.7.2015          | Exjade                           | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR,<br>United Kingdom                                   | EU/1/06/356                                | 21.7.2015         |

| Data tad-deċiżjoni | Isem tal-prodott med-<br>icinali | Detentur tal-awtorizzazzjoni għat-tqeghid fis-suq                                                                                                            | Numru tal-entrata fir-Re-<br>gistru Komunitarju | Data ta' noti-<br>fika |
|--------------------|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|------------------------|
| 17.7.2015          | HALAVEN                          | Eisai Europe Limited<br>European Knowledge Centre, Mosquito Way,<br>Hatfield, Herts AL10 9SN, United Kingdom                                                 | EU/1/11/678                                     | 21.7.2015              |
| 17.7.2015          | JETREA                           | ThromboGenics NV<br>Gaston Geenslaan 1, B-3001 Leuven, België                                                                                                | EU/1/13/819                                     | 22.7.2015              |
| 17.7.2015          | Latuda                           | Takeda Pharma A/S<br>Dybendal Alle 10, 2630 Taastrup, Danmark                                                                                                | EU/1/14/913                                     | 21.7.2015              |
| 17.7.2015          | PecFent                          | Archimedes Development Ltd<br>Albert Einstein Centre, Nottingham Science and<br>Technology Park, University Boulevard NG7 2<br>TN Nottingham, United Kingdom | EU/1/10/644                                     | 21.7.2015              |
| 17.7.2015          | Rapiscan                         | Rapidscan Pharma Solutions EU Ltd<br>Regent's Place, 338 Euston Road, London<br>NW1 3BT, United Kingdom                                                      | EU/1/10/643                                     | 21.7.2015              |
| 17.7.2015          | RoActemra                        | Roche Registration Limited<br>6 Falcon Way, Shire Park, Welwyn Garden City,<br>AL7 1TW, United Kingdom                                                       | EU/1/08/492                                     | 21.7.2015              |
| 17.7.2015          | Somavert                         | Pfizer Limited<br>Ramsgate Road, Sandwich, Kent CT13 9NJ,<br>United Kingdom                                                                                  | EU/1/02/240                                     | 21.7.2015              |
| 17.7.2015          | Sylvant                          | Janssen-Cilag International NV<br>Turnhoutseweg 30, B-2340 Beerse, België                                                                                    | EU/1/14/928                                     | 22.7.2015              |
| 17.7.2015          | Votrient                         | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR,<br>United Kingdom                                                                   | EU/1/10/628                                     | 21.7.2015              |
| 17.7.2015          | XALKORI                          | Pfizer Limited<br>Ramsgate Road, Sandwich, Kent CT13 9NJ,<br>United Kingdom                                                                                  | EU/1/12/793                                     | 21.7.2015              |
| 20.7.2015          | Lucentis                         | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR,<br>United Kingdom                                                                   | EU/1/06/374                                     | 23.7.2015              |
| 20.7.2015          | Replagal                         | Shire Human Genetic Therapies AB<br>Svärdvägen 11D, SE-182 33 Danderyd, Sverige                                                                              | EU/1/01/189                                     | 23.7.2015              |
| 20.7.2015          | Soliris                          | Alexion Europe SAS<br>1-15 avenue Edouard Belin, 92500 Rueil-Mal-<br>maison, France                                                                          | EU/1/07/393                                     | 23.7.2015              |
| 28.7.2015          | Abraxane                         | Celgene Europe Limited<br>1 Longwalk Road, Stockley Park, Uxbridge<br>UB11 1DB, United Kingdom                                                               | EU/1/07/428                                     | 30.7.2015              |
| 28.7.2015          | Brinavess                        | Cardiome UK Limited<br>Lakeside House, 1 Furzeground Way, Stockley<br>Park, Uxbridge, Middlesex, UB11 1BD, United<br>Kingdom                                 | EU/1/10/645                                     | 30.7.2015              |

| Data tad-deċiżjoni | Isem tal-prodott med-<br>icinali | Detentur tal-awtorizzazzjoni għat-tqeghid fis-suq                                                                 | Numru tal-entrata fir-Re-<br>gistru Komunitarju | Data ta' noti-<br>fika |
|--------------------|----------------------------------|-------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|------------------------|
| 28.7.2015          | Humira                           | AbbVie Ltd<br>Maidenhead, SL6 4XE, United Kingdom                                                                 | EU/1/03/256                                     | 30.7.2015              |
| 28.7.2015          | Lantus                           | Sanofi-Aventis Deutschland GmbH<br>D-65926 Frankfurt am Main, Deutschland                                         | EU/1/00/134                                     | 30.7.2015              |
| 28.7.2015          | Levemir                          | Novo Nordisk A/S<br>Novo Allé, DK-2880 Bagsvaerd, Danmark                                                         | EU/1/04/278                                     | 30.7.2015              |
| 28.7.2015          | Mycamine                         | Astellas Pharma Europe B.V.<br>Sylviusweg 62, NL-2333 BE Leiden, Nederland                                        | EU/1/08/448                                     | 30.7.2015              |
| 28.7.2015          | Neoclarityn                      | Merck Sharp & Dohme Limited<br>Hertford Road, Hoddesdon, Hertfordshire<br>EN11 9BU, United Kingdom                | EU/1/00/161                                     | 31.7.2015              |
| 28.7.2015          | Nimenrix                         | GlaxoSmithKline Biologicals S.A.<br>rue de l'Institut 89, 1330 Rixensart, Belgique                                | EU/1/12/767                                     | 31.7.2015              |
| 28.7.2015          | Opsumit                          | Actelion Registration Ltd<br>Chiswick Tower, 13th floor, 389 Chiswick High<br>Road, London W4 4AL, United Kingdom | EU/1/13/893                                     | 30.7.2015              |
| 28.7.2015          | Osigraft                         | Olympus Biotech International Limited<br>40 Upper Mount Street, Dublin 2, Ireland                                 | EU/1/01/179                                     | 30.7.2015              |
| 28.7.2015          | Perjeta                          | Roche Registration Limited<br>6 Falcon Way, Shire Park, Welwyn Garden City,<br>AL7 1TW, United Kingdom            | EU/1/13/813                                     | 30.7.2015              |
| 28.7.2015          | Prepandemic In-<br>fluenza       | Novartis Vaccines and Diagnostics S.r.l.<br>Via Fiorentina, 1, 53100 Siena, Italia                                | EU/1/10/657                                     | 31.7.2015              |
| 28.7.2015          | Stayveer                         | Marklas Nederland B.V.<br>Beneluxlaan 2b, NL-3446 GR Woerden, Neder-<br>land                                      | EU/1/13/832                                     | 30.7.2015              |
| 28.7.2015          | Temomedac                        | medac Gesellschaft für klinische Spezialpräparate<br>mbH<br>Theaterstr. 6, D-22880 Wedel, Deutschland             | EU/1/09/605                                     | 30.7.2015              |
| 28.7.2015          | Temozolomide<br>SUN              | Sun Pharmaceutical Industries Europe BV<br>Polarisavenue 87, NL-2132 JH Hoofddorp,<br>Nederland                   | EU/1/11/697                                     | 30.7.2015              |
| 28.7.2015          | Tivicay                          | ViiV Healthcare UK Limited<br>980 Great West Road, Brentford, Middlesex<br>TW8 9GS, United Kingdom                | EU/1/13/892                                     | 30.7.2015              |
| 28.7.2015          | Translarna                       | PTC Therapeutics International Limited<br>77 Sir John Rogerson's Quay, Dublin 2, Ireland                          | EU/1/13/902                                     | 30.7.2015              |
| 28.7.2015          | Vizarsin                         | Krka, d. d., Novo Mesto<br>Šmarješka cesta 6, 8501 Novo mesto, Slovenija                                          | EU/1/09/551                                     | 31.7.2015              |

| Data tad-deċiżjoni | Isem tal-prodott med-<br>diċinali | Detentur tal-awtorizzazzjoni ghat-tqeghid fis-suq                                                     | Numru tal-entrata fir-Re-<br>gistru Komunitarju | Data ta' noti-<br>fika |
|--------------------|-----------------------------------|-------------------------------------------------------------------------------------------------------|-------------------------------------------------|------------------------|
| 28.7.2015          | Votubia                           | Novartis Europharm Limited<br>Frimley Business Park, Camberley GU16 7SR,<br>United Kingdom            | EU/1/11/710                                     | 30.7.2015              |
| 28.7.2015          | Xarelto                           | Bayer Pharma AG<br>D-13342 Berlin, Deutschland                                                        | EU/1/08/472                                     | 30.7.2015              |
| 28.7.2015          | Zebinix                           | BIAL – Portela & Ca, SA<br>A Av. da Siderurgia Nacional 4745-457 S. Ma-<br>mede do Coronado, Portugal | EU/1/09/514                                     | 30.7.2015              |
| 28.7.2015          | Zytiga                            | Janssen-Cilag International NV<br>Turnhoutseweg 30, B-2340 Beerse, België                             | EU/1/11/714                                     | 30.7.2015              |
| 29.7.2015          | Glubrava                          | Takeda Pharma A/S<br>Dybendal Alle 10, 2630 Taastrup, Danmark                                         | EU/1/07/421                                     | 31.7.2015              |
| 29.7.2015          | Ketek                             | Aventis Pharma S.A.<br>20, Avenue Raymond Aron, F-92160 ANTONY,<br>France                             | EU/1/01/191                                     | 31.7.2015              |
| 31.7.2015          | Abseamed                          | Medice Arzneimittel Pütter GmbH & Co KG<br>Kuhloweg 37, D-58638 Iserlohn, Deutschland                 | EU/1/07/412                                     | 4.8.2015               |
| 31.7.2015          | Binocrit                          | Sandoz GmbH<br>Biochemiestrasse 10, A-6250 Kundl, Österreich                                          | EU/1/07/410                                     | 4.8.2015               |
| 31.7.2015          | Epoetin alfa Hexal                | Hexal AG<br>Industriestrasse 25, D-83607 Holzkirchen,<br>Deutschland                                  | EU/1/07/411                                     | 4.8.2015               |
| 31.7.2015          | Picato                            | Leo Pharma A/S<br>Industriparken 55, DK-2750 Ballerup, Danmark                                        | EU/1/12/796                                     | 4.8.2015               |
| 31.7.2015          | Voncento                          | CSL Behring GmbH<br>Emil-von-Behring-Straße 76, D-35041 Marburg,<br>Deutschland                       | EU/1/13/857                                     | 4.8.2015               |

— **Irtirar ta' awtorizzazzjoni ghat-tqeghid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill)

| Data tad-deċiżjoni | Isem tal-prodott me-<br>diċinali | Detentur tal-awtorizzazzjoni ghat-tqeghid fis-suq   | Numru tal-entrata fir-Re-<br>gistru Komunitarju | Data ta' noti-<br>fika |
|--------------------|----------------------------------|-----------------------------------------------------|-------------------------------------------------|------------------------|
| 3.7.2015           | Sonata                           | Meda AB<br>Pipers väg 2 A, S-170 09 Solna, Sverige  | EU/1/99/102                                     | 7.7.2015               |
| 13.7.2015          | Zoledronic acid<br>Teva Generics | Teva B.V.<br>Swensweg 5, 2031 GA Haarlem, Nederland | EU/1/14/912                                     | 15.7.2015              |

— **Irriġ ta' awtorizzazzjoni għat-tqeghid fis-suq** (Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | INN (Denominazzjoni Internazzjonali Komuni)                                                                                                                                                                                                | Detentur tal-awtorizzazzjoni għat-tqeghid fis-suq                                    | Numru tal-entrata fir-Reġistru Komunitarju | Forma farmaċewtika                                                  | Kodiċi ATC (Kodiċi Anatomiku Terapewtiku Kimiku) | Data ta' notifiċa |
|--------------------|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------------------------------------------|---------------------------------------------------------------------|--------------------------------------------------|-------------------|
| 3.7.2015           | Canigen L4                  | L. interrogans serogrupp Canicola serovar Portland-vere/<br>L. interrogans serogrupp Icterohaemorrhagiae serovar Copenhageni/L. interrogans serogroup Australis serovar Bratislava/<br>L. kirschneri serogrupp Grippotyphosa serovar Dadas | Intervet International B.V.<br>Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland | EU/2/15/183                                | Suspensjoni għall-injezzjoni                                        | QI07AB01                                         | 7.7.2015          |
| 3.7.2015           | Innovax-ILT                 | Herpesvirus ri-kombinant ħaj cell-associated tad-dundjan (strejn HVT/ILT-138) li jesprimi il-glycoproteini gD u gI tal-virus infettiv laryngo-tracheitis:                                                                                  | Intervet International B.V.<br>Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland | EU/2/15/182                                | Suspensjoni u solvent għal suspensjoni għall-injezzjoni għat-tigieg | QI01AD                                           | 7.7.2015          |
| 31.7.2015          | UpCard                      | Torasemide                                                                                                                                                                                                                                 | Vétoquinol SA<br>Magny-Vernois, 70200 Lure, France                                   | EU/2/15/184                                | Pillola                                                             | QC03CA04                                         | 4.8.2015          |

— **Hruġ ta' awtorizzazzjoni ghat-tqeghid fis-suq** (Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Miċhud**

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur tal-awtorizzazzjoni ghat-tqeghid fis-suq                  | Numru tal-entrata fir-Reġistru Komunitarju | Data ta' notifiċa |
|--------------------|-----------------------------|--------------------------------------------------------------------|--------------------------------------------|-------------------|
| 8.7.2015           | Lodipressin                 | Le Vet Beheer B.V.<br>Wilgenweg 7, NL-3421 TV Oudewater, Nederland | —                                          | 10.7.2015         |

— **Modifika ta' awtorizzazzjoni ghat-tqeghid fis-suq** (Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur tal-awtorizzazzjoni ghat-tqeghid fis-suq                                                                          | Numru tal-entrata fir-Reġistru Komunitarju | Data ta' notifiċa |
|--------------------|-----------------------------|----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|-------------------|
| 13.7.2015          | SevoFlo                     | Abbott Laboratories Ltd<br>Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead Berkshire SL6 4XE, United Kingdom | EU/2/02/035                                | 15.7.2015         |
| 17.7.2015          | Incurin                     | Intervet International B.V.<br>Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland                                       | EU/2/00/018                                | 21.7.2015         |
| 20.7.2015          | Contacera                   | Zoetis Belgium S.A.<br>Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique                                                 | EU/2/12/144                                | 23.7.2015         |
| 28.7.2015          | Poulvac E. coli             | Zoetis Belgium S.A.<br>Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique                                                 | EU/2/12/140                                | 30.7.2015         |
| 31.7.2015          | BTVPUR AlSap 2-4            | Merial<br>29 avenue Tony Garnier, F-69007 Lyon, France                                                                     | EU/2/10/108                                | 4.8.2015          |
| 31.7.2015          | Coxevac                     | CEVA SANTE ANIMALE<br>10 avenue de la Ballastière, F-33500 Libourne, France                                                | EU/2/10/110                                | 4.8.2015          |

— **Irtirar ta' awtorizzazzjoni ghat-tqeghid fis-suq** (Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill)

| Data tad-deċiżjoni | Isem tal-prodott mediċinali | Detentur tal-awtorizzazzjoni ghat-tqeghid fis-suq                        | Numru tal-entrata fir-Reġistru Komunitarju | Data ta' notifiċa |
|--------------------|-----------------------------|--------------------------------------------------------------------------|--------------------------------------------|-------------------|
| 8.7.2015           | ProMeris                    | Pfizer Limited<br>Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom | EU/2/06/064                                | 10.7.2015         |
| 8.7.2015           | ProMeris Duo                | Pfizer Limited<br>Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom | EU/2/06/065                                | 10.7.2015         |

Kull min jixtieq jikkonsulta r-rapport ta' evalwazzjoni pubblika dwar il-prodotti mediċinali kkonċernati u d-deċiżjonijiet marbuta magħhom għandu jikkuntattja lil:

The European Medicines Agency  
30, Churchill Place, Canary Wharf  
UK – LONDON E14 5EU

**Sommarju ta' deċiżjonijiet tal-Unjoni Ewropea dwar l-awtorizzazzjonijiet ghat-tqeghid fis-suq tal-prodotti mediċinali mill-1 ta' Lulju 2015 sal-31 ta' Lulju 2015**

(Deċiżjonijiet mehuda skont l-Artikolu 34 tad-Direttiva 2001/83/KE <sup>(1)</sup> jew l-Artikolu 38 tad-Direttiva 2001/82/KE <sup>(2)</sup>)

(2015/C 285/02)

**— Hruġ, manteniment jew modifika ta' awtorizzazzjoni ghat-tqeghid fis-suq**

| Data tad-deċiżjoni | Isem/Isimijiet tal-prodott mediċinali                                                                                                         | INN (Denominazzjoni Internazzjonali Komuni) | Detentur(i) tal-awtorizzazzjoni ghat-tqeghid fis-suq | Stat Membru kkonċernat | Data ta' notifika |
|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|------------------------------------------------------|------------------------|-------------------|
| 16.7.2015          | Prodotti mediċinali għall-użu mill-bniedem li għalihom il-parti klinika tal-istudji tal-bioekwivalenza saret mill-GVK Biosciences f'Hyderabad | Ara l-Anness I                              | Ara l-Anness I                                       | Ara l-Anness I         | 20.7.2015         |
| 17.7.2015          | Fentanyl                                                                                                                                      | Fentanyl                                    | Mhux applikabbli                                     | Mhux applikabbli       | 20.7.2015         |
| 3.7.2015           | Zoledronic acid                                                                                                                               | Zoledronic acid                             | Mhux applikabbli                                     | Mhux applikabbli       | 7.7.2015          |

**— Sospensjoni ta' awtorizzazzjoni nazzjonali ghat-tqeghid fis-suq**

| Data tad-deċiżjoni | Isem/Isimijiet tal-prodott mediċinali                                                                                                         | INN (Denominazzjoni Internazzjonali Komuni) | Detentur(i) tal-awtorizzazzjoni ghat-tqeghid fis-suq | Stat Membru kkonċernat | Data ta' notifika |
|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|------------------------------------------------------|------------------------|-------------------|
| 16.7.2015          | Prodotti mediċinali għall-użu mill-bniedem li għalihom il-parti klinika tal-istudji tal-bioekwivalenza saret mill-GVK Biosciences f'Hyderabad | Ara l-Anness I                              | Ara l-Anness I                                       | Ara l-Anness I         | 20.7.2015         |

<sup>(1)</sup> ĠU L 311, 28.11.2001, p. 67.

<sup>(2)</sup> ĠU L 311, 28.11.2001, p. 1.

## ANNEX I

Lista tal-ismijiet, għamliet farmaceutiċi, qawwiet tal-prodotti mediċinali, mnejn jingħata, id-detentur tal-awtorizzazzjoni għat-tqeghid fis-suq fl-Istati Membri

Anness IA: Prodotti li l-awtorizzazzjonijiet għat-tqeghid fis-suq tagħhom huma rakkomandati li jin jammu

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                        | INN                     | Isem Ivvintat                                        | Qawwa  | Għamla farmaċewtika                        | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------|-------------------------|------------------------------------------------------|--------|--------------------------------------------|----------------|
| L-Awstrija           | Basics GmbH<br>Hemmelrather Weg 201<br>51377 Leverkusen<br>Germany          | Venlafaksina            | Venlafaxin Ranbaxy<br>150 mg<br>Retardkapseln        | 150 mg | Kapsula li terfi l-mediċina bil-mod, iebša | Użu orali      |
| L-Awstrija           | Basics GmbH<br>Hemmelrather Weg 201<br>51377 Leverkusen<br>Germany          | Venlafaksina            | Venlafaxin Ranbaxy<br>75 mg Retardkapseln            | 75 mg  | Kapsula li terfi l-mediċina bil-mod, iebša | Użu orali      |
| L-Awstrija           | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaksina kloridrata | Venlafaxin Bluefish 75 mg<br>Hartkapseln retardiert  | 75 mg  | Kapsula li terfi l-mediċina bil-mod, iebša | Użu orali      |
| L-Awstrija           | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaksina kloridrata | Venlafaxin Bluefish 150 mg<br>Hartkapseln retardiert | 150 mg | Kapsula li terfi l-mediċina bil-mod, iebša | Użu orali      |
| L-Awstrija           | G.L. Pharma GmbH<br>Schlossplatz 1<br>8502 Lannach<br>Austria               | Nebivolol               | Nebilan 5 mg Tabletten                               | 5 mg   | Pillola                                    | Użu orali      |
| L-Awstrija           | G.L. Pharma GmbH<br>Schlossplatz 1<br>8502 Lannach<br>Austria               | Nebivolol               | Nebivolol G.L. 5 mg –<br>Tabletten                   | 5 mg   | Pillola                                    | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                        | INN           | Isem Ivvintat                          | Qawwa    | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|---------------------------------------------------------------------------------------------|---------------|----------------------------------------|----------|------------------------|----------------|
| L-Awstrija          | Ratiopharm Arzneimittel-Vertriebs-GmbH<br>Albert-Schweitzer-Gasse 3<br>1140 Wien<br>Austria | Nebivolol     | NEBIVOLOL-RATIOPHARM<br>5 MG Tabletten | 5 mg     | Pillola                | Użu orali      |
| Il-Bulgarija        | Alkaloid – INT d.o.o.<br>Slandrova 4<br>1231 Ljubljana – Črnuče<br>Slovenia                 | Levetiracetam | Lyvam                                  | 250 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Bulgarija        | Alkaloid – INT d.o.o.<br>Slandrova 4<br>1231 Ljubljana – Črnuče<br>Slovenia                 | Levetiracetam | Lyvam                                  | 500 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Bulgarija        | Alkaloid – INT d.o.o.<br>Slandrova 4<br>1231 Ljubljana – Črnuče<br>Slovenia                 | Levetiracetam | Lyvam                                  | 750 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Bulgarija        | Alkaloid – INT d.o.o.<br>Slandrova 4<br>1231 Ljubljana – Črnuče<br>Slovenia                 | Levetiracetam | Lyvam                                  | 1 000 mg | Pillola miksija b'rita | Użu orali      |
| Il-Bulgarija        | Ecopharm Group AD<br>bul. Cherni vrah 14, bl.3<br>Sofia 1421<br>Bulgaria                    | Nebivolol     | Nevolen                                | 5 mg     | Pillola                | Użu orali      |
| Il-Bulgarija        | Ewopharma International s.r.o.,<br>Hlavna 13<br>Bratislava 83101<br>Slovakia                | Feksofenadina | Ewofex                                 | 120 mg   | Pillola miksija b'rita | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                          | INN           | Isem l-vintat                        | Qawwa   | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|-------------------------------------------------------------------------------|---------------|--------------------------------------|---------|------------------------|----------------|
| Il-Bulgarija        | EvoPharma International s.r.o.,<br>Hlavna 13<br>Bratislava 83101<br>Slovakia  | Feksofenadina | Ewofex                               | 180 mg  | Pillola miksija b'rita | Użu orali      |
| Il-Bulgarija        | G.L. Pharma GmbH<br>Schlossplatz 1<br>8502 Lannach<br>Austria                 | Nebivolol     | Nebilan                              | 5 mg    | Pillola                | Użu orali      |
| Il-Bulgarija        | Neo Balkanika EOOD<br>35 Zemliane Str.<br>Sofia 1618<br>Bulgaria              | Nebivolol     | Bivolet                              | 5 mg    | Pillola                | Użu orali      |
| Il-Bulgarija        | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan      | Bosentan Sandoz                      | 62,5 mg | Pillola miksija b'rita | Użu orali      |
| Il-Bulgarija        | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan      | Bosentan Sandoz                      | 125 mg  | Pillola miksija b'rita | Użu orali      |
| Il-Kroazja          | Alkaloid d.o.o.<br>Ulica grada Vukovara 226 F<br>Zagreb 10000<br>Croatia      | Levetiracetam | Lyvam 250 mg filmom obložene tablete | 250 mg  | Pillola miksija b'rita | Użu orali      |
| Il-Kroazja          | Alkaloid d.o.o.<br>Ulica grada Vukovara 226 F<br>Zagreb 10000<br>Croatia      | Levetiracetam | Lyvam 500 mg filmom obložene tablete | 500 mg  | Pillola miksija b'rita | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                                                      | INN                       | Isem l-vintat                                 | Qawwa    | Għamla farmaċewtika    | Mnejn jingħata |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------------------------------------------|----------|------------------------|----------------|
| Il-Kroazja           | Alkaloid d.o.o.<br>Ulica grada Vukovara 226 F<br>Zagreb 10000<br>Croatia                                                                  | Levetiracetam             | Lyvam 750 mg filmom obložene tablete          | 750 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Kroazja           | Alkaloid d.o.o.<br>Ulica grada Vukovara 226 F<br>Zagreb 10000<br>Croatia                                                                  | Levetiracetam             | Lyvam 1 000 mg filmom obložene tablete        | 1 000 mg | Pillola miksija b'rita | Użu orali      |
| Ċipru                | Delorbis Pharmaceuticals Ltd<br>17 Athinon Street<br>Ergates Industrial Area<br>2643 Ergates<br>P.O. Box 28629<br>2081 Lefkosia<br>Cyprus | Levocetirizina kloridrata | Zobral                                        | 5 mg     | Pillola miksija b'rita | Użu orali      |
| Ir-Repubblika Ċeka   | Abdi Farma, Unipessoal Lda.<br>Quinta da Fonte, Rua dos Malhoes<br>2770-071 Edifício D. Pedro I<br>Paco de Arcos<br>Portugal              | Monoidrat tal-bosentan    | Bosentan Abdi 62,5 mg potahované tablety      | 62,5 mg  | Pillola miksija b'rita | Użu orali      |
| Ir-Repubblika Ċeka   | Abdi Farma, Unipessoal Lda.<br>Quinta da Fonte, Rua dos Malhoes<br>2770-071 Edifício D. Pedro I<br>Paco de Arcos<br>Portugal              | Monoidrat tal-bosentan    | Bosentan Abdi 125 mg potahované tablety       | 125 mg   | Pillola miksija b'rita | Użu orali      |
| Ir-Repubblika Ċeka   | Biofarm Sp. z o.o.<br>ul. Wałbrzyska 13<br>60-198 Poznań<br>Poland                                                                        | Levocetirizina kloridrata | Levocetirizin Biofarm 5 mg potahované tablety | 5 mg     | Pillola miksija b'rita | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                        | INN                      | Isem l-vintat                       | Qawwa  | Għamla farmaċewtika                        | Mnejn jingħata |
|---------------------|---------------------------------------------------------------------------------------------|--------------------------|-------------------------------------|--------|--------------------------------------------|----------------|
| Ir-Repubblika Ċeka  | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                 | Venlafaksina             | Venlafaxine Bluefish 75 mg          | 75 mg  | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Ir-Repubblika Ċeka  | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                 | Venlafaksina             | Venlafaxine Bluefish 150 mg         | 150 mg | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Ir-Repubblika Ċeka  | Ewopharma International s.r.o.,<br>Hlavna 13<br>Bratislava 83101<br>Slovakia                | Feksofenadina kloridrata | Ewofex 120 mg potahované tablety    | 120 mg | Pillola miksija b'rita                     | Użu orali      |
| Ir-Repubblika Ċeka  | Ewopharma International s.r.o.,<br>Hlavna 13<br>Bratislava 83101<br>Slovakia                | Feksofenadina kloridrata | Ewofex 180 mg potahované tablety    | 180 mg | Pillola miksija b'rita                     | Użu orali      |
| Ir-Repubblika Ċeka  | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam            | Letiramyl 250 mg potahované tablety | 250 mg | Pillola miksija b'rita                     | Użu orali      |
| Ir-Repubblika Ċeka  | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam            | Letiramyl 500 mg potahované tablety | 500 mg | Pillola miksija b'rita                     | Użu orali      |
| Ir-Repubblika Ċeka  | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam            | Letiramyl 750 mg potahované tablety | 750 mg | Pillola miksija b'rita                     | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                        | INN                    | Isem l-vintat                                          | Qawwa    | Għamla farmaċewtika    | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------------------|------------------------|--------------------------------------------------------|----------|------------------------|----------------|
| Ir-Repubblika Ċeka   | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam          | Letiramy <sup>1</sup> 1 000 mg pota-<br>hované tablety | 1 000 mg | Pillola miksija b'rita | Użu orali      |
| Ir-Repubblika Ċeka   | Sandoz s.r.o.<br>U Nákladového nádraží 10<br>130 00 Prague 3<br>Czech Republic              | Monoidrat tal-bosentan | Bosentan Sandoz 62,5 mg                                | 62,5 mg  | Pillola miksija b'rita | Użu orali      |
| Ir-Repubblika Ċeka   | Sandoz s.r.o.<br>U Nákladového nádraží 10<br>130 00 Prague 3<br>Czech Republic              | Monoidrat tal-bosentan | Bosentan Sandoz 125 mg                                 | 125 mg   | Pillola miksija b'rita | Użu orali      |
| Ir-Repubblika Ċeka   | Teva Pharmaceuticals CR, s.r.o.<br>Radlická 3185/1c<br>150 00 Prague 5<br>Czech Republic    | Monoidrat tal-bosentan | Bosentan Teva 125 mg po-<br>tahované tablety           | 125 mg   | Pillola miksija b'rita | Użu orali      |
| Id-Danimarka         | Alfred E. Tiefenbacher GmbH<br>Van-der-Smissen-Strasse 1<br>D-22767 Hamburg<br>Germany      | Levocetirizina         | Levocetira                                             | 5 mg     | Pillola miksija b'rita | Użu orali      |
| Id-Danimarka         | Alfred E. Tiefenbacher GmbH<br>Van-der-Smissen-Strasse 1<br>D-22767 Hamburg<br>Germany      | Levocetirizina         | Levcetin                                               | 5 mg     | Pillola miksija b'rita | Użu orali      |
| Id-Danimarka         | Biofarm Sp. z o.o.<br>ul. Wąbrzyska 13<br>60-198 Poznań<br>Poland                           | Levocetirizina         | Levrin                                                 | 5 mg     | Pillola miksija b'rita | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                               | INN                     | Isem Ivvintat        | Qawwa  | Għamla farmaċewtika                 | Mnejn jingħata |
|---------------------|------------------------------------------------------------------------------------|-------------------------|----------------------|--------|-------------------------------------|----------------|
| Id-Danimarka        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden        | Venlafaksina kloridrata | Venlafaxine Bluefish | 75 mg  | Kapsula li terhi l-medicina bil-mod | Użu orali      |
| Id-Danimarka        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden        | Venlafaksina kloridrata | Venlafaxine Bluefish | 150 mg | Kapsula li terhi l-medicina bil-mod | Użu orali      |
| Id-Danimarka        | Cipla Channele Generics Limited<br>Athenry Road,<br>Loughrea, Co Galway<br>Ireland | Feksofenadina           | Alterfast            | 120 mg | Pillola miksija b'rita              | Użu orali      |
| Id-Danimarka        | Cipla Channele Generics Limited<br>Athenry Road,<br>Loughrea, Co Galway<br>Ireland | Feksofenadina           | Alterfast            | 180 mg | Pillola miksija b'rita              | Użu orali      |
| Id-Danimarka        | Cipla Channele Generics Limited<br>Athenry Road,<br>Loughrea, Co Galway<br>Ireland | Feksofenadina           | Clarifast            | 120 mg | Pillola miksija b'rita              | Użu orali      |
| Id-Danimarka        | Cipla Channele Generics Limited<br>Athenry Road,<br>Loughrea, Co Galway<br>Ireland | Feksofenadina           | Clarifast            | 180 mg | Pillola miksija b'rita              | Użu orali      |
| Id-Danimarka        | Cipla Channele Generics Limited<br>Athenry Road,<br>Loughrea, Co Galway<br>Ireland | Feksofenadina           | Histafast            | 120 mg | Pillola miksija b'rita              | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                                                          | INN                     | Isem Ivvintat                     | Qawwa  | Għamla farmaċewtika    | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------------------|--------|------------------------|----------------|
| Id-Danimarka         | Cipla Channele Generics Limited<br>Athenry Road,<br>Loughrea, Co Galway<br>Ireland                                                            | Feksofenadina           | Histafast                         | 180 mg | Pillola miksija b'rita | Użu orali      |
| Id-Danimarka         | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                                                                    | Feksofenadina           | Nefoxef                           | 120 mg | Pillola miksija b'rita | Użu orali      |
| Id-Danimarka         | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                                                                    | Feksofenadina           | Nefoxef                           | 180 mg | Pillola miksija b'rita | Użu orali      |
| Id-Danimarka         | Norton Healthcare Ltd T/A Ivax Pharmaceuticals UK<br>Ridings Point, Whistler Drive<br>Castleford<br>West Yorkshire WF10 5HX<br>United Kingdom | Feksofenadina           | Fexofenadinhydrochlorid<br>"Ivax" | 120 mg | Pillola miksija b'rita | Użu orali      |
| Id-Danimarka         | Norton Healthcare Ltd T/A Ivax Pharmaceuticals UK<br>Ridings Point, Whistler Drive<br>Castleford<br>West Yorkshire WF10 5HX<br>United Kingdom | Feksofenadina           | Fexofenadinhydrochlorid<br>"Ivax" | 180 mg | Pillola miksija b'rita | Użu orali      |
| Id-Danimarka         | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark                                                                              | Metoklopramid kloridrat | Metoclopramide Orifarm            | 10 mg  | Pillola                | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                     | INN           | Isem Ivvintat     | Qawwa   | Għamla farmaċewtika                         | Mnejn jingħata |
|----------------------|--------------------------------------------------------------------------|---------------|-------------------|---------|---------------------------------------------|----------------|
| Id-Danimarka         | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark         | Feksofenadina | Altifex           | 120 mg  | Pillola miksija b'rita                      | Użu orali      |
| Id-Danimarka         | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark         | Feksofenadina | Altifex           | 180 mg  | Pillola miksija b'rita                      | Użu orali      |
| L-Estonja            | G.L. Pharma GmbH<br>Schlossplatz 1<br>8502 Lannach<br>Austria            | Nebivolol     | NEBITEN 5 MG      | 5 mg    | Pillola                                     | Użu orali      |
| L-Estonja            | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland | Venlafaksina  | VENLAFAXINE ORION | 37,5 mg | Kapsula li terfi l-medicina bil-mod, iebbsa | Użu orali      |
| L-Estonja            | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland | Venlafaksina  | VENLAFAXINE ORION | 75 mg   | Kapsula li terfi l-medicina bil-mod, iebbsa | Użu orali      |
| L-Estonja            | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland | Venlafaksina  | VENLAFAXINE ORION | 150 mg  | Kapsula li terfi l-medicina bil-mod, iebbsa | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                          | INN                     | Isem Ivvintat                | Qawwa   | Għamla farmaċewtika                        | Mnejn jingħata |
|---------------------|-------------------------------------------------------------------------------|-------------------------|------------------------------|---------|--------------------------------------------|----------------|
| L-Estonja           | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan                | BOSENTAN SANDOZ              | 62,5 mg | Pillola miksija b'rita                     | Użu orali      |
| L-Estonja           | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan                | BOSENTAN SANDOZ              | 125 mg  | Pillola miksija b'rita                     | Użu orali      |
| L-Estonja           | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                   | Bosentan                | BOSENTAN NORAMEDA<br>62,5 MG | 62,5 mg | Pillola miksija b'rita                     | Użu orali      |
| L-Estonja           | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                   | Bosentan                | BOSENTAN NORAMEDA<br>125 MG  | 125 mg  | Pillola miksija b'rita                     | Użu orali      |
| L-Estonja           | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany    | Venlafaksina            | VENLAGAMMA 75 MG             | 75 mg   | Kapsula li terfi l-medicina bil-mod, iebsa | Użu orali      |
| L-Estonja           | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany    | Venlafaksina            | VENLAGAMMA 150 MG            | 150 mg  | Kapsula li terfi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Finlandja        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden   | Venlafaksina kloridrata | Venlafaxine Bluefish         | 75 mg   | Kapsula li terfi l-medicina bil-mod, iebsa | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                   | INN                     | Isem Ivvintat                                    | Qawwa   | Għamla farmaċewtika                        | Mnejn jingħata |
|----------------------|----------------------------------------------------------------------------------------|-------------------------|--------------------------------------------------|---------|--------------------------------------------|----------------|
| Il-Finlandja         | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden            | Venlafaksina kloridrata | Venlafaxine Bluefish                             | 150 mg  | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Finlandja         | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                             | Feksofenadina           | Nefoxef                                          | 120 mg  | Pillola miksija b'rīta                     | Użu orali      |
| Il-Finlandja         | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland               | Venlafaksina kloridrata | VENLAFAXIN ORION                                 | 37,5 mg | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Finlandja         | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland               | Venlafaksina kloridrata | VENLAFAXIN ORION                                 | 75 mg   | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Finlandja         | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland               | Venlafaksina kloridrata | VENLAFAXIN ORION                                 | 150 mg  | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Franza               | Alfred E. Tiefenbacher GmbH<br>Van-der-Smissen-Strasse 1<br>D-22767 Hamburg<br>Germany | Levocetirizina          | Levocetira 5 mg comprimé pelliculé               | 5 mg    | Pillola miksija b'rīta                     | Użu orali      |
| Franza               | BIOGARAN<br>15, boulevard Charles de Gaulle<br>92707 Colombes Cedex                    | Feksofenadina           | FEXOFENADINE BIOGARAN 120 mg, comprimé pelliculé | 120 mg  | Pillola miksija b'rīta                     | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                          | INN           | Isem Ivvintat                                           | Qawwa    | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------------------|---------------|---------------------------------------------------------|----------|------------------------|----------------|
| Franza              | BIOGARAN<br>15, boulevard Charles de Gaulle<br>92707 Colombes Cedex                           | Feksofenadina | FEXOFENADINE BIOGARAN 180 mg, comprimé pelliculé        | 180 mg   | Pillola miksija b'rita | Użu orali      |
| Franza              | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                        | Feksofenadina | FEXOFENADINE MYLAN 120 Film-coated Tablet               | 120 mg   | Pillola miksija b'rita | Użu orali      |
| Franza              | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                        | Feksofenadina | FEXOFENADINE MYLAN 180 Film-coated Tablet               | 180 mg   | Pillola miksija b'rita | Użu orali      |
| Franza              | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                        | Levetiracetam | LEVETIRACETAM MYLAN PHARMA 250 mg, comprimé pelliculé   | 250 mg   | Pillola                | Użu orali      |
| Franza              | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                        | Levetiracetam | LEVETIRACETAM MYLAN PHARMA 500 mg, comprimé pelliculé   | 500 mg   | Pillola                | Użu orali      |
| Franza              | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                        | Levetiracetam | LEVETIRACETAM MYLAN PHARMA 1 000 mg, comprimé pelliculé | 1 000 mg | Pillola                | Użu orali      |
| Franza              | Plus Pharmacie SA<br>26 Boulevard Paul Vaillant-Couturier<br>F-94200 Ivry-sur-Seine<br>France | NEBIVOLOL     | NEBIVOLOL ISOMED 5 mg, comprimé quadriséable            | 5 mg     | Pillola                | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                       | INN           | Isem Ivvintat                                                    | Qawwa   | Għamla farmaċewtika                  | Mnejn jingħata |
|---------------------|------------------------------------------------------------------------------------------------------------|---------------|------------------------------------------------------------------|---------|--------------------------------------|----------------|
| Franza              | Ranbaxy Pharmacie Generiques<br>11-15 Quai Dion Bouton<br>92800 Puteaux<br>France                          | Venlafaksina  | Venlafaxine Ranbaxy LP<br>37,5 mg, gélule à libération prolongée | 37,5 mg | Kapsula li terfhi l-medicina bil-mod | Użu orali      |
| Franza              | Ranbaxy Pharmacie Generiques<br>11-15 Quai Dion Bouton<br>92800 Puteaux<br>France                          | Venlafaksina  | Venlafaxine Ranbaxy LP<br>75 mg, gélule à libération prolongée   | 75 mg   | Kapsula li terfhi l-medicina bil-mod | Użu orali      |
| Franza              | Ranbaxy Pharmacie Generiques<br>11-15 Quai Dion Bouton<br>92800 Puteaux<br>France                          | Venlafaksina  | Venlafaxine Ranbaxy LP<br>150 mg, gélule à libération prolongée  | 150 mg  | Kapsula li terfhi l-medicina bil-mod | Użu orali      |
| Franza              | Ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>D-89079 Ulm<br>Germany                                           | NEBIVOLOL     | NEBIVOLOL RATIOPHARM<br>5 mg, comprimé quadrisé-cable            | 5 mg    | Pillola                              | Użu orali      |
| Franza              | Teva Sante<br>Cœur Défense – 100-110<br>Esplanade du Général de Gaulle<br>92931 La Défense Cedex<br>France | Feksofenadina | FEXOFENADINE TEVA 120<br>Film-coated Tablet                      | 120 mg  | Pillola miksija b'rita               | Użu orali      |
| Franza              | Teva Sante<br>Cœur Défense – 100-110<br>Esplanade du Général de Gaulle<br>92931 La Défense Cedex<br>France | Feksofenadina | FEXOFENADINE TEVA 180<br>Film-coated Tablet                      | 180 mg  | Pillola miksija b'rita               | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                   | INN            | Isem l-vintat                                        | Qawwa   | Għamla farmaċewtika                         | Mnejn jingħata |
|----------------------|----------------------------------------------------------------------------------------|----------------|------------------------------------------------------|---------|---------------------------------------------|----------------|
| Il-Ġermanja          | AAA-Pharma GmbH<br>Liebknechtstrasse 33<br>70565 Stuttgart<br>Germany                  | Venlafaksina   | Venlafaxin AAA 75 mg<br>Hartkapseln, retardiert      | 75 mg   | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Ġermanja          | AAA-Pharma GmbH<br>Liebknechtstrasse 33<br>70565 Stuttgart<br>Germany                  | Venlafaksina   | Venlafaxin AAA 150 mg<br>Hartkapseln, retardiert     | 150 mg  | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Ġermanja          | AAA-Pharma GmbH<br>Liebknechtstrasse 33<br>70565 Stuttgart<br>Germany                  | Venlafaksina   | Venlafaxin AAA 37,5 mg<br>Hartkapseln, retardiert    | 37,5 mg | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Ġermanja          | Alfred E. Tiefenbacher GmbH<br>Van-der-Smissen-Strasse 1<br>D-22767 Hamburg<br>Germany | Levocetirizina | Levocetira 5 mg Filmtabletten                        | 5 mg    | Pillola miksija b'rīta                      | Użu orali      |
| Il-Ġermanja          | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden            | Venlafaksina   | Venlafaxin Bluefish 75 mg<br>Hartkapsel, retardiert  | 75 mg   | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Ġermanja          | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden            | Venlafaksina   | Venlafaxin Bluefish 150 mg<br>Hartkapsel, retardiert | 15 mg   | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Ġermanja          | Dermapharm Aktiengesellschaft<br>Lil-Dagover-Ring 7<br>82031 Grünwald<br>Germany       | Feksofenadina  | Fexofenaderm 120 mg<br>Filmtabletten                 | 120 mg  | Pillola miksija b'rīta                      | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                     | INN           | Isem Ivvintat                                                    | Qawwa   | Għamla farmaċewtika                               | Mnejn jingħata |
|----------------------|----------------------------------------------------------------------------------------------------------|---------------|------------------------------------------------------------------|---------|---------------------------------------------------|----------------|
| Il-Ġermanja          | Dermapharm Aktiengesellschaft<br>Lil-Dagover-Ring 7<br>82031 Grünwald<br>Germany                         | Feksofenadina | Fexofenaderm 180 mg<br>Filmdabletten                             | 180 mg  | Pillola miksija b'rita                            | Użu orali      |
| Il-Ġermanja          | Farmaprojects, S.A.U.<br>Santa Eulalia, 240-242 L'Hospitalet de<br>Llobregat<br>08902 Barcelona<br>Spain | Venlafaksina  | Venlafaxin Farmaprojects<br>37,5 mg Hartkapseln, retar-<br>diert | 37,5 mg | Kapsula li terhi l-<br>medicina bil-mod,<br>iebsa | Użu orali      |
| Il-Ġermanja          | Farmaprojects, S.A.U.<br>Santa Eulalia, 240-242 L'Hospitalet de<br>Llobregat<br>08902 Barcelona<br>Spain | Venlafaksina  | Venlafaxin Farmaprojects<br>75 mg Hartkapseln, retar-<br>diert   | 75 mg   | Kapsula li terhi l-<br>medicina bil-mod,<br>iebsa | Użu orali      |
| Il-Ġermanja          | Farmaprojects, S.A.U.<br>Santa Eulalia, 240-242 L'Hospitalet de<br>Llobregat<br>08902 Barcelona<br>Spain | Venlafaksina  | Venlafaxin Farmaprojects<br>150 mg Hartkapseln, retar-<br>diert  | 150 mg  | Kapsula li terhi l-<br>medicina bil-mod,<br>iebsa | Użu orali      |
| Il-Ġermanja          | G.L. Pharma GmbH<br>Schlossplatz 1<br>8502 Lannach<br>Austria                                            | Nebivolol     | NEBITEN 5 MG                                                     | 5 mg    | Pillola                                           | Użu orali      |
| Il-Ġermanja          | Heumann Pharma GmbH & Co. Gene-<br>rica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                | Venlafaksina  | Venlafaxin Heumann<br>37,5 mg Hartkapseln, retar-<br>diert       | 37,5 mg | Kapsula li terhi l-<br>medicina bil-mod,<br>iebsa | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                         | INN           | Isem l-vintat                                     | Qawwa    | Għamla farmaċewtika                         | Mnejn jingħata |
|---------------------|----------------------------------------------------------------------------------------------|---------------|---------------------------------------------------|----------|---------------------------------------------|----------------|
| Il-Ġermanja         | Heumann Pharma GmbH & Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany         | Venlafaksina  | Venlafaxin Heumann 75 mg Hartkapseln, retardiert  | 75 mg    | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Ġermanja         | Heumann Pharma GmbH & Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany         | Venlafaksina  | Venlafaxin Heumann 150 mg Hartkapseln, retardiert | 150 mg   | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Ġermanja         | Heumann Pharma GmbH & Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany         | Nebivolol     | Nebivolol Heumann 5 mg Tabletten                  | 5 mg     | Pillola                                     | Użu orali      |
| Il-Ġermanja         | Hormosan Pharma GmbH<br>Wilhelmshoeher Str. 106<br>D-60389 Frankfurt<br>06 Hessen<br>Germany | Levetiracetam | Levetiracetam-Hormosan 500 mg Filmtabletten       | 500 mg   | Pillola miksija b'rita                      | Użu orali      |
| Il-Ġermanja         | Hormosan Pharma GmbH<br>Wilhelmshoeher Str. 106<br>D-60389 Frankfurt<br>06 Hessen<br>Germany | Levetiracetam | Levetiracetam-Hormosan 750 mg Filmtabletten       | 750 mg   | Pillola miksija b'rita                      | Użu orali      |
| Il-Ġermanja         | Hormosan Pharma GmbH<br>Wilhelmshoeher Str. 106<br>D-60389 Frankfurt<br>06 Hessen<br>Germany | Levetiracetam | Levetiracetam-Hormosan 1 000 mg Filmtabletten     | 1 000 mg | Pillola miksija b'rita                      | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                         | INN           | Isem Ivvintat                                        | Qawwa   | Għamla farmaċewtika                               | Mnejn jingħata |
|----------------------|----------------------------------------------------------------------------------------------|---------------|------------------------------------------------------|---------|---------------------------------------------------|----------------|
| Il-Ġermanja          | Hormosan Pharma GmbH<br>Wilhelmshoeher Str. 106<br>D-60389 Frankfurt<br>06 Hessen<br>Germany | Levetiracetam | Levetiracetam-Hormosan<br>250 mg Filmtabletten       | 250 mg  | Pillola miksija b'rita                            | Użu orali      |
| Il-Ġermanja          | Lannacher Heilmittel Ges.m.b.H.<br>Schlossplatz 1<br>8502 Lannach<br>Austria                 | Nebivolol     | Nebivolol Lannacher 5 mg<br>Tabletten                | 5 mg    | Pillola                                           | Użu orali      |
| Il-Ġermanja          | Ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>D-89079 Ulm<br>Germany                             | Nebivolol     | NEBIVOLOL-RATIOPHARM<br>5 MG                         | 5 mg    | Pillola                                           | Użu orali      |
| Il-Ġermanja          | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                           | Nebivolol     | Nebivolol Torrent 5 mg Ta-<br>bletten                | 5 mg    | Pillola                                           | Użu orali      |
| Il-Ġermanja          | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany                   | Venlafaksina  | Venlagamma retard 37,5 mg<br>Hartkapseln, retardiert | 37,5 mg | Kapsula li terhi l-<br>medicina bil-mod,<br>iebsa | Użu orali      |
| Il-Ġermanja          | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany                   | Venlafaksina  | Venlagamma retard 75 mg<br>Hartkapseln, retardiert   | 75 mg   | Kapsula li terhi l-<br>medicina bil-mod,<br>iebsa | Użu orali      |
| Il-Ġermanja          | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany                   | Venlafaksina  | Venlagamma retard 150 mg<br>hartkapseln, retardiert  | 150 mg  | Kapsula li terhi l-<br>medicina bil-mod,<br>iebsa | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                        | INN           | Isem l-vintat                                                              | Qawwa  | Għamla farmaċewtika                        | Mnejn jingħata |
|---------------------|---------------------------------------------------------------------------------------------|---------------|----------------------------------------------------------------------------|--------|--------------------------------------------|----------------|
| Il-Greċja           | Pharmazac SA<br>31 Naoussis street<br>Athens 1447<br>Greece                                 | Venlafaksina  | Zacalen pr cap<br>75 mg/cap                                                | 75 mg  | Kapsula li terġi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Greċja           | Pharmazac SA<br>31 Naoussis street<br>Athens 1447<br>Greece                                 | Venlafaksina  | Zacalen pr cap<br>150 mg/cap                                               | 150 mg | Kapsula li terġi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Greċja           | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                          | Nebivolol     | Nebivolol Torrent 5 mg                                                     | 5 mg   | Pillola                                    | Użu orali      |
| L-Ungerija          | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                 | Venlafaksina  | Venlafaxin Bluefish 150 mg<br>nyújtott hatóanyagleadású<br>kemény kapszula | 150 mg | Kapsula li terġi l-medicina bil-mod, iebsa | Użu orali      |
| L-Ungerija          | Ewopharma International s.r.o.,<br>Hlavná 13<br>Bratislava 83101<br>Slovakia                | Feksofenadina | Ewofex 180 mg filmtabletta                                                 | 180 mg | Pillola miksija b'rita                     | Użu orali      |
| L-Ungerija          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Feksofenadina | Fexgen 120 mg filmtabletta                                                 | 120 mg | Pillola miksija b'rita                     | Użu orali      |
| L-Ungerija          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Feksofenadina | Fexgen 180 mg filmtabletta                                                 | 180 mg | Pillola miksija b'rita                     | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                        | INN                     | Isem Ivvintat                                | Qawwa   | Għamla farmaċewtika                        | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------|-------------------------|----------------------------------------------|---------|--------------------------------------------|----------------|
| L-Ungerija           | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany          | Nebivolol               | Nebivolol Torrent 5 mg                       | 5 mg    | Pillola                                    | Użu orali      |
| L-Ungerija           | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany  | Venlafaksina            | Venlagamma 37,5 mg retard<br>kemény kapszula | 37,5 mg | Kapsula li terfi l-medicina bil-mod, iebša | Użu orali      |
| L-Ungerija           | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany  | Venlafaksina            | Venlagamma 75 mg retard<br>kemény kapszula   | 75 mg   | Kapsula li terfi l-medicina bil-mod, iebša | Użu orali      |
| L-Ungerija           | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany  | Venlafaksina            | Venlagamma 150 mg retard<br>kemény kapszula  | 150 mg  | Kapsula li terfi l-medicina bil-mod, iebša | Użu orali      |
| L-Islanda            | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaksina kloridrata | Venlafaxine Bluefish                         | 150 mg  | Kapsula li terfi l-medicina bil-mod, iebša | Użu orali      |
| L-Islanda            | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaksina kloridrata | Venlafaxine Bluefish                         | 37,5 mg | Kapsula li terfi l-medicina bil-mod, iebša | Użu orali      |
| L-Islanda            | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaksina kloridrata | Venlafaxine Bluefish                         | 75 mg   | Kapsula li terfi l-medicina bil-mod, iebša | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                          | INN                      | Isem Ivvintat                                         | Qawwa  | Għamla farmaċewtika                  | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------------------|--------------------------|-------------------------------------------------------|--------|--------------------------------------|----------------|
| L-Islanda            | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                    | Feksofenadina            | Nefoxef                                               | 120 mg | Pillola miksija b'rita               | Użu orali      |
| L-Islanda            | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                    | Feksofenadina            | Nefoxef                                               | 180 mg | Pillola miksija b'rita               | Użu orali      |
| L-Irlanda            | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-111 23 Stockholm<br>Sweden                  | Venlafaksina kloridrata  | Venlablue XL 75 mg, prolonged release capsules, hard  | 75 mg  | Kapsula li terfhi l-medicina bil-mod | Użu orali      |
| L-Irlanda            | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-111 23 Stockholm<br>Sweden                  | Venlafaksina kloridrata  | Venlablue XL 150 mg, prolonged release capsules, hard | 150 mg | Kapsula li terfhi l-medicina bil-mod | Użu orali      |
| L-Irlanda            | Chanelle Medical<br>Dublin road<br>Loughrea, Co. Galway<br>Ireland                            | Feksofenadina kloridrata | Fexofenadine hydrochloride 120 mg Film-Coated tablets | 120 mg | Pillola miksija b'rita               | Użu orali      |
| L-Irlanda            | Chanelle Medical<br>Dublin road<br>Loughrea, Co. Galway<br>Ireland                            | Feksofenadina kloridrata | Fexofenadine hydrochloride 180 mg Film-coated tablets | 180 mg | Pillola miksija b'rita               | Użu orali      |
| L-Irlanda            | Morningside Healthcare Limited<br>115 Narborough Road<br>Leicester, LE3 0PA<br>United Kingdom | Venlafaksina kloridrata  | Vensir XL 75 mg prolonged-release hard capsules       | 75 mg  | Kapsula li terfhi l-medicina bil-mod | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                          | INN                     | Isem Ivvintat                                    | Qawwa  | Għamla farmaċewtika                          | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------------------|-------------------------|--------------------------------------------------|--------|----------------------------------------------|----------------|
| L-Irlanda            | Morningside Healthcare Limited<br>115 Narborough Road<br>Leicester, LE3 0PA<br>United Kingdom | Venlafaksina kloridrata | Vensir XL 150 mg prolonged-release hard capsules | 150 mg | Kapsula li terfhi l-medicina bil-mod         | Użu orali      |
| L-Italja             | Alfred E. Tiefenbacher GmbH<br>Van-der-Smissen-Strasse 1<br>D-22767 Hamburg<br>Germany        | Levocetirizina          | Levcetin 5 mg compresse rivestite con film       | 5 mg   | Pillola miksija b'rita                       | Użu orali      |
| L-Italja             | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                   | Venlafaksina            | VENLAFAXINA ABC                                  | 75 mg  | Kapsula li terfhi l-medicina bil-mod, iebbsa | Użu orali      |
| L-Italja             | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                   | Venlafaksina            | VENLAFAXINA ABC                                  | 150 mg | Kapsula li terfhi l-medicina bil-mod, iebbsa | Użu orali      |
| L-Italja             | Costanzafarma S.R.L.<br>Via Taranto, 4<br>20142 Milan<br>Italy                                | Feksofenadina           | FIXODIN                                          | 120 mg | Pillola miksija b'rita                       | Użu orali      |
| L-Italja             | Costanzafarma S.R.L.<br>Via Taranto, 4<br>20142 Milan<br>Italy                                | Feksofenadina           | FIXODIN                                          | 180 mg | Pillola miksija b'rita                       | Użu orali      |
| L-Italja             | FB Health S.p.A.<br>Via dei Sabini, 28<br>63100 – Ascoli Piceno<br>Italy                      | Venlafaksina            | IXILANIA                                         | 75 mg  | Kapsula li terfhi l-medicina bil-mod, iebbsa | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                | INN           | Isem Ivvintat                | Qawwa    | Għamla farmaċewtika                        | Mnejn jinghata |
|---------------------|-------------------------------------------------------------------------------------|---------------|------------------------------|----------|--------------------------------------------|----------------|
| L-Italja            | FB Health S.p.A.<br>Via dei Sabini, 28<br>63100 – Ascoli Piceno<br>Italy            | Venlafaksina  | IXILANIA                     | 150 mg   | Kapsula li terfi l-mediċina bil-mod, iebsa | Użu orali      |
| L-Italja            | Germel Pharma S.P.A.<br>Via Cantu', 11<br>Cinisello Balsamo<br>Milan 20092<br>Italy | Nebivolol     | NEBIVOLOLO GERMED            | 5 mg     | Pillola                                    | Użu orali      |
| L-Italja            | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                       | Levetiracetam | LEVETIRACETAM MYLAN GENERICS | 250 mg   | Pillola miksija b'rġa                      | Użu orali      |
| L-Italja            | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                       | Levetiracetam | LEVETIRACETAM MYLAN GENERICS | 750 mg   | Pillola miksija b'rġa                      | Użu orali      |
| L-Italja            | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                       | Levetiracetam | LEVETIRACETAM MYLAN GENERICS | 500 mg   | Pillola miksija b'rġa                      | Użu orali      |
| L-Italja            | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                       | Levetiracetam | LEVETIRACETAM MYLAN GENERICS | 1 000 mg | Pillola miksija b'rġa                      | Użu orali      |
| L-Italja            | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                       | Feksofenadina | FEXOFEENADINA MYLAN GENERICS | 120 mg   | Pillola miksija b'rġa                      | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                          | INN           | Isem Ivvintat                   | Qawwa  | Għamla farmaċewtika                         | Mnejn jingħata |
|---------------------|-------------------------------------------------------------------------------|---------------|---------------------------------|--------|---------------------------------------------|----------------|
| L-Italja            | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                 | Feksofenadina | FEXOFENADINA MYLAN<br>GENERICIS | 180 mg | Pillola miksija b'rita                      | Użu orali      |
| L-Italja            | Pensa Pharma S.P.A.<br>Via Rossellini Ippolito, 12<br>20124 Milan<br>Italy    | Venlafaksina  | VENLAFAXINA PENSA               | 75 mg  | Kapsula li terfi l-medicina bil-mod, iebbsa | Użu orali      |
| L-Italja            | Pensa Pharma S.P.A.<br>Via Rossellini Ippolito, 12<br>20124 Milan<br>Italy    | Venlafaksina  | VENLAFAXINA PENSA               | 150 mg | Kapsula li terfi l-medicina bil-mod, iebbsa | Użu orali      |
| L-Italja            | Progefarm S.r.l.<br>Largo Donegani 4/A<br>28100 – Novara<br>Italy             | Venlafaksina  | VENLAFAXINA PROGE<br>FARM       | 75 mg  | Kapsula li terfi l-medicina bil-mod, iebbsa | Użu orali      |
| L-Italja            | Progefarm S.r.l.<br>Largo Donegani 4/A<br>28100 – Novara<br>Italy             | Venlafaksina  | VENLAFAXINA PROGE<br>FARM       | 150 mg | Kapsula li terfi l-medicina bil-mod, iebbsa | Użu orali      |
| L-Italja            | Ranbaxy Italia S.P.A.<br>Piazza Filippo Meda, 4, 3<br>20121 – Milano<br>Italy | Venlafaksina  | VENLAFAXINA RANBAXY<br>GENERICI | 75 mg  | Kapsula li terfi l-medicina bil-mod, iebbsa | Użu orali      |
| L-Italja            | Ranbaxy Italia S.P.A.<br>Piazza Filippo Meda, 4, 3<br>20121 – Milano<br>Italy | Venlafaksina  | VENLAFAXINA RANBAXY<br>GENERICI | 150 mg | Kapsula li terfi l-medicina bil-mod, iebbsa | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                          | INN          | Isem l-vintat                                                        | Qawwa   | Għamla farmaċewtika                               | Mnejn jingħata |
|---------------------|-------------------------------------------------------------------------------|--------------|----------------------------------------------------------------------|---------|---------------------------------------------------|----------------|
| L-Italja            | Ranbaxy Italia S.P.A.<br>Piazza Filippo Meda, 4, 3<br>20121 – Milano<br>Italy | Lansoprazol  | Lansoprazolo<br>Ranbaxy 15 mg<br>capsule rigide<br>gastrorresistenti | 15 mg   | Pillola gastro-reżis-<br>tenti                    | Użu orali      |
| L-Italja            | Ranbaxy Italia S.P.A.<br>Piazza Filippo Meda, 4, 3<br>20121 – Milano<br>Italy | Lansoprazol  | Lansoprazolo<br>Ranbaxy 30 mg<br>capsule rigide<br>gastrorresistenti | 30 mg   | Pillola gastro-reżis-<br>tenti                    | Użu orali      |
| Il-Latvja           | G.L. Pharma GmbH<br>Schlossplatz 1<br>8502 Lannach<br>Austria                 | Nebivolol    | Nebiten                                                              | 5 mg    | Pillola                                           | Użu orali      |
| Il-Latvja           | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland      | Venlafaksina | Venlafaxine Orion                                                    | 37,5 mg | Kapsula li terfi l-<br>medicina bil-mod,<br>iebsa | Użu orali      |
| Il-Latvja           | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland      | Venlafaksina | Venlafaxine Orion                                                    | 75 mg   | Kapsula li terfi l-<br>medicina bil-mod,<br>iebsa | Użu orali      |
| Il-Latvja           | Ranbaxy UK Ltd.<br>20 Balderton Street<br>London W1K 6TL<br>Untied Kingdom    | Lansoprazol  | Lanobax 30 mg gastro-re-<br>sistant capsules, hard                   | 30 mg   | Pillola gastro-reżis-<br>tenti                    | Użu orali      |
| Il-Latvja           | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan     | Bosentan Sandoz                                                      | 62,5 mg | Pillola miksija b'rita                            | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                          | INN          | Isem Ivvintat     | Qawwa   | Għamla farmaċewtika                        | Mnejn jingħata |
|---------------------|-------------------------------------------------------------------------------|--------------|-------------------|---------|--------------------------------------------|----------------|
| Il-Latvja           | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan     | Bosentan Sandoz   | 125 mg  | Pillola miksija b'rita                     | Użu orali      |
| Il-Latvja           | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                   | Bosentan     | Bosentan Norameda | 62,5 mg | Pillola miksija b'rita                     | Użu orali      |
| Il-Latvja           | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                   | Bosentan     | Bosentan Norameda | 125 mg  | Pillola miksija b'rita                     | Użu orali      |
| Il-Litwanja         | G.L. Pharma GmbH<br>Schlossplatz 1<br>8502 Lannach<br>Austria                 | Nebivolol    | Nebiten           | 5 mg    | Pillola                                    | Użu orali      |
| Il-Litwanja         | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland      | Venlafaksina | Venlafaxine Orion | 37,5 mg | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Litwanja         | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland      | Venlafaksina | Venlafaxine Orion | 75 mg   | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Litwanja         | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland      | Venlafaksina | Venlafaxine Orion | 150 mg  | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                       | INN                     | Isem Ivvintat          | Qawwa   | Għamla farmaċewtika                        | Mnejn jingħata |
|---------------------|------------------------------------------------------------------------------------------------------------|-------------------------|------------------------|---------|--------------------------------------------|----------------|
| Il-Litwanja         | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>Untied Kingdom | Lansoprazol             | LANOBAX                | 30 mg   | Pillola gastro-reżistenti                  | Użu orali      |
| Il-Litwanja         | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia                              | Bosentan                | Bosentan Sandoz        | 62,5 mg | Pillola miksija b'rīta                     | Użu orali      |
| Il-Litwanja         | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia                              | Bosentan                | Bosentan Sandoz        | 125 mg  | Pillola miksija b'rīta                     | Użu orali      |
| Il-Litwanja         | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                                         | Nebivolol               | Nebivolol Torrent 5 mg | 5 mg    | Pillola                                    | Użu orali      |
| Il-Litwanja         | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                                                | Bosentan                | Bosentan Norameda      | 62,5 mg | Pillola miksija b'rīta                     | Użu orali      |
| Il-Litwanja         | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                                                | Bosentan                | Bosentan Norameda      | 125 mg  | Pillola miksija b'rīta                     | Użu orali      |
| In-Norveġja         | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                | Venlafaksina kloridrata | Venlafaxin Bluefish    | 75 mg   | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                        | INN                      | Isem Ivvintat           | Qawwa  | Għamla farmaċewtika                         | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------|--------------------------|-------------------------|--------|---------------------------------------------|----------------|
| In-Norveġja          | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaksina kloridrata  | Venlafaxin Bluefish     | 150 mg | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| In-Norveġja          | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark            | Metoklopramid kloridrat  | Metoclopramide Orifarm  | 10 mg  | Pillola                                     | Użu orali      |
| In-Norveġja          | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark            | Feksofenadina kloridrata | Altifex                 | 120 mg | Pillola miksija b'rita                      | Użu orali      |
| In-Norveġja          | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark            | Feksofenadina kloridrata | Altifex                 | 180 mg | Pillola miksija b'rita                      | Użu orali      |
| Il-Polonja           | Biofarm Sp. z o.o.<br>ul. Walbrzyska 13<br>60-198 Poznań<br>Poland          | Levocetirizina           | Zyx                     | 5 mg   | Pillola miksija b'rita                      | Użu orali      |
| Il-Polonja           | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaksina             | Venlafaxine Bluefish XL | 75 mg  | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Polonja           | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaksina             | Venlafaxine Bluefish XL | 150 mg | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                        | INN                      | Isem Ivvintat          | Qawwa    | Għamla farmaċewtika    | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------------------|--------------------------|------------------------|----------|------------------------|----------------|
| Il-Polonja           | Celon Pharma S.A.<br>Ogrodowa 2 A, Kielpin<br>05-092 Łomianki,<br>Poland                    | Bosentan                 | Bosentan Celon         | 125 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Polonja           | Farmaceutyczna Spółdzielnia Pracy Gailena<br>Krucza 62<br>50-984 Wrocław<br>Poland          | Feksofenadina kloridrata | Fexofast 120 mg        | 120 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Polonja           | Farmaceutyczna Spółdzielnia Pracy Gailena<br>Krucza 62<br>50-984 Wrocław<br>Poland          | Feksofenadina kloridrata | Fexofast 180 mg        | 180 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Polonja           | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam            | Levetiracetam-Generics | 250 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Polonja           | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam            | Levetiracetam-Generics | 500 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Polonja           | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam            | Levetiracetam-Generics | 750 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Polonja           | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam            | Levetiracetam-Generics | 1 000 mg | Pillola miksija b'rita | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                        | INN           | Isem Ivvintat | Qawwa   | Għamla farmaċewtika                        | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------------------|---------------|---------------|---------|--------------------------------------------|----------------|
| Il-Polonja           | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Feksofenadina | FexoGen       | 120 mg  | Pillola miksija b'rīta                     | Użu orali      |
| Il-Polonja           | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Feksofenadina | FexoGen       | 180 mg  | Pillola miksija b'rīta                     | Użu orali      |
| Il-Polonja           | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                    | Venlafaksina  | Oriven        | 37,5 mg | Kapsula li terħi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Polonja           | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                    | Venlafaksina  | Oriven        | 75 mg   | Kapsula li terħi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Polonja           | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                    | Venlafaksina  | Oriven        | 150 mg  | Kapsula li terħi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Polonja           | Ranbaxy (Poland) Sp. z o.o.<br>Kubickiego 11<br>02-954 Warszawa<br>Poland                   | Lansoprazol   | LANBAX        | 15 mg   | Pillola gastro-reżis-tenti                 | Użu orali      |
| Il-Polonja           | Ranbaxy (Poland) Sp. z o.o.<br>Kubickiego 11<br>02-954 Warszawa<br>Poland                   | Lansoprazol   | LANBAX        | 30 mg   | Pillola gastro-reżis-tenti                 | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                       | INN          | Isem Ivvintat   | Qawwa   | Għamla farmaċewtika                         | Mnejn jingħata |
|---------------------|----------------------------------------------------------------------------|--------------|-----------------|---------|---------------------------------------------|----------------|
| Il-Polonja          | Ranbaxy (Poland) Sp. z o.o.<br>Kubickiego 11<br>02-954 Warszawa<br>Poland  | Venlafaksina | Venlabax MR     | 37,5 mg | Kapsula li terfhi l-medicina bil-mod        | Użu orali      |
| Il-Polonja          | Ranbaxy (Poland) Sp. z o.o.<br>Kubickiego 11<br>02-954 Warszawa<br>Poland  | Venlafaksina | Venlabax MR     | 75 mg   | Kapsula li terfhi l-medicina bil-mod        | Użu orali      |
| Il-Polonja          | Ranbaxy (Poland) Sp. z o.o.<br>Kubickiego 11<br>02-954 Warszawa<br>Poland  | Venlafaksina | Venlabax MR     | 150 mg  | Kapsula li terfhi l-medicina bil-mod        | Użu orali      |
| Il-Polonja          | Sandoz GmbH<br>Biochemiestrasse 10<br>A-6250 Kundl<br>Austria              | Bosentan     | Bosentan Sandoz | 62,5 mg | Pillola miksija b'rita                      | Użu orali      |
| Il-Polonja          | Sandoz GmbH<br>Biochemiestrasse 10<br>A-6250 Kundl<br>Austria              | Bosentan     | Bosentan Sandoz | 125 mg  | Pillola miksija b'rita                      | Użu orali      |
| Il-Polonja          | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany | Venlafaksina | Venlagamma      | 75 mg   | Kapsula li terfhi l-medicina bil-mod, iebša | Użu orali      |
| Il-Polonja          | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany | Venlafaksina | Venlagamma      | 37,5 mg | Kapsula li terfhi l-medicina bil-mod, iebša | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                           | INN                      | Isem Ivvintat           | Qawwa  | Għamla farmaċewtika                        | Mnejn jingħata |
|----------------------|----------------------------------------------------------------------------------------------------------------|--------------------------|-------------------------|--------|--------------------------------------------|----------------|
| Il-Polonja           | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany                                     | Venlafaksina             | Venlagamma              | 150 mg | Kapsula li terfi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Polonja           | Zakłady Farmaceutyczne POLPHARMA<br>S.A. Pelpińska 19<br>83-200 Starogard Gdański<br>Poland                    | Feksofenadina kloridrata | Telfexo 120 mg          | 120 mg | Pillola miksija b'rita                     | Użu orali      |
| Il-Polonja           | Zakłady Farmaceutyczne POLPHARMA<br>S.A. Pelpińska 19<br>83-200 Starogard Gdański<br>Poland                    | Feksofenadina kloridrata | Telfexo 180 mg          | 180 mg | Pillola miksija b'rita                     | Użu orali      |
| Il-Portugall         | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                    | Venlafaksina             | Venlafaxina Bluefish XR | 75 mg  | Kapsula li terfi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Portugall         | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                    | Venlafaksina             | Venlafaxina Bluefish XR | 150 mg | Kapsula li terfi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Portugall         | Bluepharma Genéricos – Comércio de Medicamentos, S.A.<br>São Martinho do Bispo<br>3045-016 Coimbra<br>Portugal | Venlafaksina             | Venlafaxina Bluepharma  | 150 mg | Kapsula li terfi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Portugall         | Bluepharma Genéricos – Comércio de Medicamentos, S.A.<br>São Martinho do Bispo<br>3045-016 Coimbra<br>Portugal | Venlafaksina             | Venlafaxina Bluepharma  | 75 mg  | Kapsula li terfi l-medicina bil-mod, iebsa | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                                                            | INN          | Isem Ivvintat          | Qawwa   | Għamla farmaċewtika                         | Mnejn jingħata |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------------------|---------|---------------------------------------------|----------------|
| Il-Portugall        | Bluepharma Genéricos – Comércio de Medicamentos, S.A.<br>São Martinho do Bispo<br>3045-016 Coimbra<br>Portugal                                  | Venlafaksina | Venlafaxina Bluepharma | 37,5 mg | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Portugall        | Eurogenus Farmacêutica, Sociedade Unipessoal, Lda.<br>Rua Alto do Montijo, 13 – 2º Dto.,<br>Edifício Monsanto<br>2790-012 Carnaxide<br>Portugal | Venlafaksina | Venlafaxina Eurogenus  | 37,5 mg | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Portugall        | Eurogenus Farmacêutica, Sociedade Unipessoal, Lda.<br>Rua Alto do Montijo, 13 – 2º Dto.,<br>Edifício Monsanto<br>2790-012 Carnaxide<br>Portugal | Venlafaksina | Venlafaxina Eurogenus  | 75 mg   | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Portugall        | Eurogenus Farmacêutica, Sociedade Unipessoal, Lda.<br>Rua Alto do Montijo, 13 – 2º Dto.,<br>Edifício Monsanto<br>2790-012 Carnaxide<br>Portugal | Venlafaksina | Venlafaxina Eurogenus  | 150 mg  | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Portugall        | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal                                                             | Nebivolol    | Nebivolol Generis      | 5 mg    | Pillola                                     | Użu orali      |
| Il-Portugall        | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal                                                             | Nebivolol    | Nebivolol Inventis     | 5 mg    | Pillola                                     | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                                                                   | INN                     | Isem Ivvintat        | Qawwa   | Għamla farmaċewtika                       | Mnejn jingħata |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|---------|-------------------------------------------|----------------|
| Il-Portugall         | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal                                                                    | Feksofenadina           | Fexofenadina Generis | 180 mg  | Pillola miksija b'rita                    | Użu orali      |
| Il-Portugall         | Germel Farmacêutica, Lda.<br>Rua Alto do Montijo, 13 – 1º Dto –<br>Edifício Monsanto Portela de Carnaxide<br>2790-012 Portela de Carnaxide<br>Portugal | Nebivolol               | Nebivolol Germel     | 5 mg    | Pillola                                   | Użu orali      |
| Il-Portugall         | GP – Genéricos Portugueses, Lda.<br>Rua Henrique Paiva Couceiro, 29 –<br>Venda Nova<br>2700-451 Amadora<br>Portugal                                    | Nebivolol               | Nebivolol GP         | 5 mg    | Pillola                                   | Użu orali      |
| Il-Portugall         | Labesfal, Genéricos, S.A.<br>Av. Dr. Afonso Costa, n° 1370<br>3465-051 Campo de Besteiros<br>Portugal                                                  | Venlafaksina kloridrata | Venlafaxina Labesfal | 37,5 mg | Pillola li terhi il-me-<br>dicina bil-mod | Użu orali      |
| Il-Portugall         | Labesfal, Genéricos, S.A.<br>Av. Dr. Afonso Costa, n° 1370<br>3465-051 Campo de Besteiros<br>Portugal                                                  | Venlafaksina kloridrata | Venlafaxina Labesfal | 75 mg   | Pillola li terhi il-me-<br>dicina bil-mod | Użu orali      |
| Il-Portugall         | Labesfal, Genéricos, S.A.<br>Av. Dr. Afonso Costa, n° 1370<br>3465-051 Campo de Besteiros<br>Portugal                                                  | Venlafaksina kloridrata | Venlafaxina Labesfal | 150 mg  | Pillola li terhi il-me-<br>dicina bil-mod | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                                                          | INN                      | Isem Ivvintat                       | Qawwa  | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-------------------------------------|--------|------------------------|----------------|
| Il-Portugall        | Labesfal, Genéricos, S.A.<br>Av. Dr. Afonso Costa, n° 1370<br>3465-051 Campo de Besteiros<br>Portugal                                         | Nebivolol                | Nebivolol Labesfal                  | 5 mg   | Pillola                | Użu orali      |
| Il-Portugall        | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida<br>D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal              | Feksofenadina            | Fexofenadina Mylan                  | 120 mg | Pillola miksija b'rita | Użu orali      |
| Il-Portugall        | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida<br>D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal              | Feksofenadina            | Fexofenadina Mylan                  | 180 mg | Pillola miksija b'rita | Użu orali      |
| Il-Portugall        | Ratiopharm – Comércio e Indústria de<br>Produtos Farmacêuticos, Lda.<br>Lagoas Park, Edifício 5 A, Piso 2<br>2740-245 Porto Salvo<br>Portugal | Nebivolol                | Nebivolol Ratiopharm                | 5 mg   | Pillola                | Użu orali      |
| Ir-Rumanija         | Ewopharma International s.r.o.,<br>Hlavna 13<br>Bratislava 83101<br>Slovakia                                                                  | Feksofenadina kloridrata | Ewofex 120 mg comprimate<br>filmate | 120 mg | Pillola miksija b'rita | Użu orali      |
| Ir-Rumanija         | Ewopharma International s.r.o.,<br>Hlavna 13<br>Bratislava 83101<br>Slovakia                                                                  | Feksofenadina kloridrata | Ewofex 180 mg comprimate<br>filmate | 180 mg | Pillola miksija b'rita | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                       | INN          | Isem Ivvintat                                                  | Qawwa   | Għamla farmaċewtika                        | Mnejn jingħata |
|---------------------|------------------------------------------------------------------------------------------------------------|--------------|----------------------------------------------------------------|---------|--------------------------------------------|----------------|
| Ir-Rumanija         | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>United Kingdom | Lansoprazol  | LEVANT                                                         | 15 mg   | Pillola gastro-reżistenti                  | Użu orali      |
| Ir-Rumanija         | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>United Kingdom | Lansoprazol  | LEVANT                                                         | 30 mg   | Pillola gastro-reżistenti                  | Użu orali      |
| Ir-Rumanija         | Terapia SA<br>Str. Fabricii nr. 124<br>Cluj Napoca<br>România                                              | Venlafaksina | Venlafaxina Terapia 37,5 mg<br>capsule cu eliberare prelungită | 37,5 mg | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Ir-Rumanija         | Terapia SA<br>Str. Fabricii nr. 124<br>Cluj Napoca<br>România                                              | Venlafaksina | Venlafaxina Terapia 75 mg<br>capsule cu eliberare prelungită   | 75 mg   | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Ir-Rumanija         | Terapia SA<br>Str. Fabricii nr. 124<br>Cluj Napoca<br>România                                              | Venlafaksina | Venlafaxina Terapia 150 mg<br>capsule cu eliberare prelungită  | 150 mg  | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Ir-Rumanija         | Torrent Pharma SRL<br>Str. Stirbei Voda nr. 36<br>et. 2, biroul A, sector 1<br>Bucharest<br>Romania        | Nebivolol    | Nebivolol Torrent com pri-mate                                 | 5 mg    | Pillola                                    | Użu orali      |

| Stat Membru (fl-EEA)   | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                        | INN           | Isem Ivvintat                                                               | Qawwa   | Għamla farmaċewtika                         | Mnejn jingħata |
|------------------------|---------------------------------------------------------------------------------------------|---------------|-----------------------------------------------------------------------------|---------|---------------------------------------------|----------------|
| Ir-Rumanija            | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany                  | Venlafaksina  | Venlagamma 37,5 mg capsules<br>sule cu eliberare prelungita                 | 37,5 mg | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Ir-Rumanija            | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany                  | Venlafaksina  | Venlagamma 75 mg capsules<br>cu eliberare prelungita                        | 75 mg   | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Ir-Rumanija            | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany                  | Venlafaksina  | Venlagamma 150 mg capsules<br>sule cu eliberare prelungita                  | 150 mg  | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Ir-Repubblika Slovakka | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                 | Venlafaksina  | Venlafaxine Bluefish XR<br>75 mg tvrdé kapsuly<br>s predĺženým uvoľňovaním  | 75 mg   | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Ir-Repubblika Slovakka | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                 | Venlafaksina  | Venlafaxine Bluefish XR<br>150 mg tvrdé kapsuly<br>s predĺženým uvoľňovaním | 150 mg  | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Ir-Repubblika Slovakka | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Feksofenadina | Fexofenadin Generics<br>120 mg                                              | 120 mg  | Pillola miksija b'rita                      | Użu orali      |
| Ir-Repubblika Slovakka | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Feksofenadina | Fexofenadin Generics<br>180 mg                                              | 160 mg  | Pillola miksija b'rita                      | Użu orali      |

| Stat Membru (fl-EEA)    | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                        | INN           | Isem Ivvintat                            | Qawwa    | Għamla farmaċewtika                         | Mnejn jingħata |
|-------------------------|-----------------------------------------------------------------------------|---------------|------------------------------------------|----------|---------------------------------------------|----------------|
| Ir-Repubblika Slovakkja | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany  | Venlafaksina  | Venlagamma 37,50 mg                      | 37,5 mg  | Kapsula li terfhi l-medicina bil-mod, iebša | Użu orali      |
| Ir-Repubblika Slovakkja | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany  | Venlafaksina  | Venlagamma 75 mg                         | 75 mg    | Kapsula li terfhi l-medicina bil-mod, iebša | Użu orali      |
| Ir-Repubblika Slovakkja | Wörwag Pharma GmbH & Co. KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany  | Venlafaksina  | Venlagamma 150 mg                        | 150 mg   | Kapsula li terfhi l-medicina bil-mod, iebša | Użu orali      |
| Is-Slovenja             | Alkaloid – INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana – Črnuče<br>Slovenia | Levetiracetam | Lyvam 250 mg filmisko obložene tablete   | 250 mg   | Pillola miksija b'rita                      | Użu orali      |
| Is-Slovenja             | Alkaloid – INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana – Črnuče<br>Slovenia | Levetiracetam | Lyvam 500 mg filmisko obložene tablete   | 500 mg   | Pillola miksija b'rita                      | Użu orali      |
| Is-Slovenja             | Alkaloid – INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana – Črnuče<br>Slovenia | Levetiracetam | Lyvam 750 mg filmisko obložene tablete   | 750 mg   | Pillola miksija b'rita                      | Użu orali      |
| Is-Slovenja             | Alkaloid – INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana – Črnuče<br>Slovenia | Levetiracetam | Lyvam 1 000 mg filmisko obložene tablete | 1 000 mg | Pillola miksija b'rita                      | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                      | INN          | Isem Ivvintat                                                                         | Qawwa   | Għamla farmaċewtika                         | Mnejn jingħata |
|----------------------|-------------------------------------------------------------------------------------------|--------------|---------------------------------------------------------------------------------------|---------|---------------------------------------------|----------------|
| Is-Slovenja          | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia             | Bosentan     | Bosentan Sandoz 62,5 mg<br>filmsko obložene tablete                                   | 62,5 mg | Pillola miksija b'rita                      | Użu orali      |
| Is-Slovenja          | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia             | Bosentan     | Bosentan Sandoz 125 mg<br>filmsko obložene tablete                                    | 125 mg  | Pillola miksija b'rita                      | Użu orali      |
| Is-Slovenja          | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                               | Bosentan     | Bosentan Norameda<br>125 mg filmsko obložene<br>tablete                               | 125 mg  | Pillola miksija b'rita                      | Użu orali      |
| Is-Slovenja          | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                               | Bosentan     | Bosentan Norameda<br>62,5 mg filmsko obložene<br>tablete                              | 62,5 mg | Pillola miksija b'rita                      | Użu orali      |
| Spanja               | Aristo Pharma Iberia, S.L.,<br>c/Solana, 26, Torrejon de Ardoz,<br>Madrid, 28850<br>Spain | Nebivolol    | NEBIVOLOL EDIGEN 5 mg<br>COMPRIMIDOS EFG                                              | 5 mg    | Pillola                                     | Użu orali      |
| Spanja               | Aristo Pharma Iberia, S.L.,<br>c/Solana, 26, Torrejon de Ardoz,<br>Madrid, 28850<br>Spain | Venlafaksina | VENLAFAXINA RETARD<br>URLABS 150 mg CAPSULAS<br>DURAS DE LIBERACION<br>PROLONGADA EFG | 150 mg  | Kapsula li terfi l-medicina bil-mod, iebbsa | Użu orali      |
| Spanja               | Aristo Pharma Iberia, S.L.,<br>c/Solana, 26, Torrejon de Ardoz,<br>Madrid, 28850<br>Spain | Venlafaksina | VENLAFAXINA RETARD<br>URLABS 75 mg CAPSULAS<br>DURAS DE LIBERACION<br>PROLONGADA EFG  | 75 mg   | Kapsula li terfi l-medicina bil-mod, iebbsa | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                      | INN           | Isem Ivvintat                                                                                   | Qawwa  | Għamla farmaċewtika                                | Mnejn jinghata |
|----------------------|-----------------------------------------------------------------------------------------------------------|---------------|-------------------------------------------------------------------------------------------------|--------|----------------------------------------------------|----------------|
| Spanja               | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                               | Venlafaksina  | VENLAFAXINA BLUEFISH<br>150 mg CAPSULAS DE<br>LIBERACION PROLONGA-<br>DA EFG                    | 150 mg | Kapsula li terfhi l-<br>medicina bil-mod           | Użu orali      |
| Spanja               | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                               | Venlafaksina  | VENLAFAXINA BLUEFISH<br>75 mg CAPSULAS DE LI-<br>BERACION PROLONGADA<br>EFG                     | 75 mg  | Kapsula li terfhi l-<br>medicina bil-mod           | Użu orali      |
| Spanja               | Laboratorios Ranbaxy, S. L. U.<br>Paseig de Gracia 9<br>7a Pl<br>Barcelona 08007<br>Spain                 | Venlafaksina  | VENLAFAXINA RETARD<br>RANBAXYGEN 75 MG<br>CAPSULAS DURAS DE LI-<br>BERACION PROLONGADA<br>EFG   | 75 mg  | Kapsula li terfhi l-<br>medicina bil-mod,<br>iebsa | Użu orali      |
| Spanja               | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16 0PF<br>United Kingdom   | Levetiracetam | LEVETIRACETAM LUPIN<br>750 MG COMPRIMIDOS<br>RECUBIERTOS CON PELI-<br>CULA EFG                  | 750 mg | Pillola miksija b'rita                             | Użu orali      |
| Spanja               | Pharmagenus, S.A.,<br>Avda. Camí Real, 51-57,<br>08184 Palau-solita i Plegamans (Barce-<br>lona)<br>Spain | Venlafaksina  | VENLAFAXINA RETARD<br>PHARMAGENUS 150 mg<br>CAPSULAS DURAS DE LI-<br>BERACION PROLONGADA<br>EFG | 150 mg | Kapsula li terfhi l-<br>medicina bil-mod,<br>iebsa | Użu orali      |
| Spanja               | Pharmagenus, S.A.,<br>Avda. Camí Real, 51-57,<br>08184 Palau-solita i Plegamans (Barce-<br>lona)<br>Spain | Venlafaksina  | VENLAFAXINA RETARD<br>PHARMAGENUS 75 mg<br>CAPSULAS DURAS DE LI-<br>BERACION PROLONGADA<br>EFG  | 75 mg  | Kapsula li terfhi l-<br>medicina bil-mod,<br>iebsa | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                                   | INN           | Isem l-vintat                                                               | Qawwa    | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------------------------------------------------------|----------|------------------------|----------------|
| Spanja              | RATIOPHARM ESPAÑA, S.A.<br>C/Anabel Segura, 11<br>Edificio Albatros B, 1ª planta<br>28108 Alcobendas (Madrid)<br>Spain | Nebivolol     | NEBIVOLOL RATIO 5 mg<br>COMPRIMIDOS EFG                                     | 5 mg     | Pillola                | Użu orali      |
| Spanja              | Teva Pharma S.L.U.<br>C/Anabel Segura, 11<br>Edificio Albatros B, 1ª planta<br>Madrid 28108<br>Spain                   | Feksofenadina | FEXOFENADINA TEVAGEN<br>120 mg COMPRIMIDOS<br>RECUBIERTOS CON PELÍCULA EFG  | 120 mg   | Pillola miksija b'rita | Użu orali      |
| Spanja              | Teva Pharma S.L.U.<br>C/Anabel Segura, 11<br>Edificio Albatros B, 1ª planta<br>Madrid 28108<br>Spain                   | Feksofenadina | FEXOFENADINA TEVAGEN<br>180 mg COMPRIMIDOS<br>RECUBIERTOS CON PELÍCULA EFG  | 180 mg   | Pillola miksija b'rita | Użu orali      |
| Spanja              | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                                    | Levetiracetam | LEVETIRACETAM LUPIN<br>1 000 MG COMPRIMIDOS<br>RECUBIERTOS CON PELÍCULA EFG | 1 000 mg | Pillola miksija b'rita | Użu orali      |
| Spanja              | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                                    | Levetiracetam | LEVETIRACETAM LUPIN<br>250 MG COMPRIMIDOS<br>RECUBIERTOS CON PELÍCULA EFG   | 250 mg   | Pillola miksija b'rita | Użu orali      |
| Spanja              | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                                    | Levetiracetam | LEVETIRACETAM LUPIN<br>500 MG COMPRIMIDOS<br>RECUBIERTOS CON PELÍCULA EFG   | 500 mg   | Pillola miksija b'rita | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                        | INN                     | Isem Ivvintat               | Qawwa   | Għamla farmaċewtika                        | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------|-------------------------|-----------------------------|---------|--------------------------------------------|----------------|
| L-Isvezja            | Alternova A/S<br>Lodshusvej 11<br>DK-4230 Skælskør<br>Denmark               | Bendroflumetijazid      | Bendroflumetiazid Alternova | 2,5 mg  | Pillola                                    | Użu orali      |
| L-Isvezja            | Alternova A/S<br>Lodshusvej 11<br>DK-4230 Skælskør<br>Denmark               | Bendroflumetijazid      | Bendroflumetiazid Alternova | 5 mg    | Pillola                                    | Użu orali      |
| L-Isvezja            | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaksina kloridrata | Venlafaxin Bluefish         | 37,5 mg | Kapsula li terfi l-medicina bil-mod, iebsa | Użu orali      |
| L-Isvezja            | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaksina kloridrata | Venlafaxin Bluefish         | 75 mg   | Kapsula li terfi l-medicina bil-mod, iebsa | Użu orali      |
| L-Isvezja            | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaksina kloridrata | Venlafaxin Bluefish         | 150 mg  | Kapsula li terfi l-medicina bil-mod, iebsa | Użu orali      |
| L-Isvezja            | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Feksofenadina           | Nefoxef                     | 120 mg  | Pillola miksija b'rīta                     | Użu orali      |
| L-Isvezja            | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Feksofenadina           | Nefoxef                     | 160 mg  | Pillola miksija b'rīta                     | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                       | INN                      | Isem l-vintat                                     | Qawwa  | Għamla farmaċewtika                        | Mnejn jingħata |
|---------------------|------------------------------------------------------------------------------------------------------------|--------------------------|---------------------------------------------------|--------|--------------------------------------------|----------------|
| L-Isvezja           | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark                                           | Metoklopramid kloridrat  | Metoclopramide Orifarm                            | 10 mg  | Pillola                                    | Użu orali      |
| L-Isvezja           | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark                                           | Feksofenadina kloridrata | Altifex                                           | 120 mg | Pillola miksija b'rita                     | Użu orali      |
| L-Isvezja           | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark                                           | Feksofenadina kloridrata | Altifex                                           | 180 mg | Pillola miksija b'rita                     | Użu orali      |
| L-Isvezja           | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>United Kingdom | Venlafaksina             | Venlafaxin Ranbaxy<br>150 mg depotkapsel,<br>hård | 150 mg | Kapsula li terfi l-medicina bil-mod, iebsa | Użu orali      |
| L-Isvezja           | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>United Kingdom | Venlafaksina             | Venlafaxin Ranbaxy<br>75 mg depotkapsel,<br>hård  | 75 mg  | Kapsula li terfi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Alfred E. Tiefenbacher GmbH<br>Van-der-Smissen-Strasse 1<br>D-22767 Hamburg<br>Germany                     | Levocetirizina           | Levocetira 5 mg filmomhulde tablet                | 5 mg   | Pillola miksija b'rita                     | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                  | INN           | Isem l-vintat                                                           | Qawwa   | Għamla farmaċewtika                        | Mnejn jingħata |
|---------------------|-------------------------------------------------------------------------------------------------------|---------------|-------------------------------------------------------------------------|---------|--------------------------------------------|----------------|
| Il-Pajjiżi l-Baxxi  | Apothecon B.V.<br>Nijverheidsweg 3<br>3771 ME Barneveld<br>The Netherlands                            | Feksofenadina | Fexofenadine HCL 120 A, fil-momhulde tabletten 120 mg                   | 120 mg  | Pillola miksija b'rita                     | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Apothecon B.V.<br>Nijverheidsweg 3<br>3771 ME Barneveld<br>The Netherlands                            | Feksofenadina | Fexofenadine HCL 180 A, fil-momhulde tabletten 120 mg                   | 180 mg  | Pillola miksija b'rita                     | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                           | Venlafaksina  | Venlafaxine Bluefish 37,5 mg, capsules met verlengde afgifte, hard      | 37,5 mg | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                           | Venlafaksina  | Venlafaxine Bluefish 37,5 mg, capsules met verlengde afgifte, hard      | 75 mg   | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                           | Venlafaksina  | Venlafaxine Bluefish 37,5 mg, capsules met verlengde afgifte, hard      | 150 mg  | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Farmaprojects, S.A.U.<br>Santa Eulalia, 240-242 L'Hospitalet de Llobregat<br>08902 Barcelona<br>Spain | Venlafaksina  | Venlafaxine Farmaprojects 37,5 mg, capsules met verlengde afgifte, hard | 37,5 mg | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                       | INN           | Isem Ivvintat                                                             | Qawwa  | Għamla farmaċewtika                         | Mnejn jingħata |
|---------------------|------------------------------------------------------------------------------------------------------------|---------------|---------------------------------------------------------------------------|--------|---------------------------------------------|----------------|
| Il-Pajjiżi l-Baxxi  | Farmaprojects, S.A.U.<br>Santa Eulalia, 240-242 L'Hospitalet de Llobregat<br>08902 Barcelona<br>Spain      | Venlafaksina  | Venlafaxine Farmaprojects<br>75 mg, capsules met verlengde afgifte, hard  | 75 mg  | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Farmaprojects, S.A.U.<br>Santa Eulalia, 240-242 L'Hospitalet de Llobregat<br>08902 Barcelona<br>Spain      | Venlafaksina  | Venlafaxine Farmaprojects<br>150 mg, capsules met verlengde afgifte, hard | 150 mg | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Mylan B.V.<br>Dieselweg 25<br>3752 LB Bunschoten<br>The Netherlands                                        | Feksofenadina | Fexofenadine HCL Mylan<br>120 mg, filmomhulde tabletten                   | 120 mg | Pillola miksija b'rita                      | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Mylan B.V.<br>Dieselweg 25<br>3752 LB Bunschoten<br>The Netherlands                                        | Feksofenadina | Fexofenadine HCL Mylan<br>180 mg, filmomhulde tabletten                   | 180 mg | Pillola miksija b'rita                      | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Pharmachemie B.V.<br>Swensweg 5<br>2031 GA Haarlem<br>The Netherlands                                      | Feksofenadina | Fexofenadine HCl 120 PCH, filmomhulde tabletten<br>120 mg                 | 120 mg | Pillola miksija b'rita                      | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Pharmachemie B.V.<br>Swensweg 5<br>2031 GA Haarlem<br>The Netherlands                                      | Feksofenadina | Fexofenadine HCl 180 PCH, filmomhulde tabletten<br>120 mg                 | 180 mg | Pillola miksija b'rita                      | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>United Kingdom | Lansoprazol   | Lansoprazol Ranbaxy<br>15 mg, maagsapresistente capsules                  | 15 mg  | Pillola gastro-rezistenti                   | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                       | INN                     | Isem Ivvintat                                                  | Qawwa   | Għamla farmaċewtika                        | Mnejn jingħata |
|---------------------|------------------------------------------------------------------------------------------------------------|-------------------------|----------------------------------------------------------------|---------|--------------------------------------------|----------------|
| Il-Pajjiżi l-Baxxi  | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>Untied Kingdom | Lansoprazol             | Lansoprazol Ranbaxy<br>30 mg,<br>maagsapresistente<br>capsules | 30 mg   | Pillola gastro-reżistenti                  | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>Untied Kingdom | Venlafaksina            | Venlafaxine Ranbaxy 75 mg,<br>capsules met verlengde afgifte   | 75 mg   | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>Untied Kingdom | Venlafaksina            | Venlafaxine Ranbaxy<br>150 mg, capsules met verlengde afgifte  | 150 mg  | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Il-Pajjiżi l-Baxxi  | Ratiopharm Nederland B.V.<br>Swensweg 5<br>2031 GA Haarlem<br>The Netherlands                              | Feksofenadina           | Fexofenadine HCl ratiopharm 120 mg, filmomhulde tabletten      | 120 mg  | Pillola miksija b'rita                     | Użu orali      |
| Ir-Renju Unit       | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                | Venlafaksina kloridrata | Venlablue XL 37,5 mg Prolonged Release Capsules Hard           | 37,5 mg | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| Ir-Renju Unit       | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                | Venlafaksina kloridrata | Venlablue XL 75 mg Prolonged Release Capsules Hard             | 75 mg   | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                     | INN                     | Isem Ivvintat                                         | Qawwa  | Għamla farmaċewtika                                  | Mnejn jinghata |
|----------------------|----------------------------------------------------------------------------------------------------------|-------------------------|-------------------------------------------------------|--------|------------------------------------------------------|----------------|
| Ir-Renju Unit        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-111 23 Stockholm<br>Sweden                             | Venlafaksina kloridrata | Venlablue XL 150 mg Prolonged Release Capsules Hard   | 150 mg | Kapsula li terfhi il-medicina bil-mod, iebsa         | Użu orali      |
| Ir-Renju Unit        | Chanelle Medical<br>Dublin road<br>Loughrea, Co. Galway<br>Ireland                                       | Feksofenadina           | Fexofenadine 120 mg film-coated tablets               | 120 mg | Pillola miksija b'rita                               | Użu orali      |
| Ir-Renju Unit        | Chanelle Medical<br>Dublin road<br>Loughrea, Co. Galway<br>Ireland                                       | Feksofenadina           | Fexofenadine 180 mg film-coated tablets               | 180 mg | Pillola miksija b'rita                               | Użu orali      |
| Ir-Renju Unit        | Forum Products Limited<br>Crown House<br>2-8 Gloucester Road<br>Redhill Surrey RH1 1FH<br>United Kingdom | Venlafaksina kloridrata | Foraven XL 75 mg Modified Release Capsules            | 75 mg  | Kapsula li terfhi il-medicina b'mod modifikat, iebsa | Użu orali      |
| Ir-Renju Unit        | Forum Products Limited<br>Crown House<br>2-8 Gloucester Road<br>Redhill Surrey RH1 1FH<br>United Kingdom | Venlafaksina kloridrata | Foraven XL 150 mg Modified Release Capsules           | 150 mg | Kapsula li terfhi il-medicina b'mod modifikat, iebsa | Użu orali      |
| Ir-Renju Unit        | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom              | Feksofenadina           | Fexofenadine hydrochloride 120 mg Film-coated tablets | 120 mg | Pillola miksija b'rita                               | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                    | INN                     | Isem Ivvintat                                            | Qawwa    | Għamla farmaċewtika                         | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------------------------------|-------------------------|----------------------------------------------------------|----------|---------------------------------------------|----------------|
| Ir-Renju Unit        | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom             | Feksofenadina           | Fexofenadine hydrochloride<br>180 mg Film-coated tablets | 180 mg   | Pillola miksija b'rita                      | Użu orali      |
| Ir-Renju Unit        | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16 0PF<br>United Kingdom | Levetiracetam           | Levetiracetam Lupin<br>250 mg Film-coated tablets        | 250 mg   | Pillola miksija b'rita                      | Użu orali      |
| Ir-Renju Unit        | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16 0PF<br>United Kingdom | Levetiracetam           | Levetiracetam Lupin<br>500 mg Film-coated tablets        | 500 mg   | Pillola miksija b'rita                      | Użu orali      |
| Ir-Renju Unit        | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16 0PF<br>United Kingdom | Levetiracetam           | Levetiracetam Lupin<br>750 mg Film-coated tablets        | 750 mg   | Pillola miksija b'rita                      | Użu orali      |
| Ir-Renju Unit        | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16 0PF<br>United Kingdom | Levetiracetam           | Levetiracetam Lupin<br>1 000 mg Film-coated tablets      | 1 000 mg | Pillola miksija b'rita                      | Użu orali      |
| Ir-Renju Unit        | Morningside Healthcare Limited<br>115 Narborough Road<br>Leicester, LE3 0PA<br>United Kingdom           | Venlafaksina kloridrata | Vensir XL 75 mg Prolonged Release Hard Capsules          | 75 mg    | Kapsula li terfi l-medicina bil-mod, iebbsa | Użu orali      |
| Ir-Renju Unit        | Morningside Healthcare Limited<br>115 Narborough Road<br>Leicester, LE3 0PA<br>United Kingdom           | Venlafaksina kloridrata | Vensir XL 150 mg Prolonged Release Hard Capsules         | 150 mg   | Kapsula li terfi l-medicina bil-mod, iebbsa | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                  | INN           | Isem l-vvintat                          | Qawwa  | Għamla farmaċewtika    | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------------|---------------|-----------------------------------------|--------|------------------------|----------------|
| Ir-Renju Unit        | Teva UK Limited<br>Brampton Road<br>Hampden Park<br>Sussex BN22 9AG<br>United Kingdom | Feksofenadina | Fexofenadine 120 mg film-coated tablets | 120 mg | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit        | Teva UK Limited<br>Brampton Road<br>Hampden Park<br>Sussex BN22 9AG<br>United Kingdom | Feksofenadina | Fexofenadine 180 mg film-coated tablets | 180 mg | Pillola miksija b'rita | Użu orali      |

**Anness IB: Prodotti li l-awtorizzazzjonijiet għat-tqegħid fis-suq tagħhom huma rakkomandati li jiġu sospi ċi**

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                         | INN                  | Isem l-vvintat                                          | Qawwa | Għamla farmaċewtika               | Mnejn jingħata |
|----------------------|------------------------------------------------------------------------------|----------------------|---------------------------------------------------------|-------|-----------------------------------|----------------|
| L-Awstrija           | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria | Ežomeprazol manježju | Esomeprazol Arcana 20 mg magensafresistente Hartkapseln | 20 mg | Kapsula gastro-režis-tenti, iebsa | Użu orali      |
| L-Awstrija           | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria | Ežomeprazol manježju | Esomeprazol Arcana 40 mg magensafresistente Hartkapseln | 40 mg | Kapsula gastro-režis-tenti, iebsa | Użu orali      |
| L-Awstrija           | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria | Ežomeprazol manježju | Neximyl 20 mg magensafresistente Hartkapseln            | 20 mg | Kapsula gastro-režis-tenti, iebsa | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                        | INN                    | Isem l-vintat                                   | Qawwa  | Għamla farmaċewtika              | Mnejn jingħata |
|---------------------|---------------------------------------------------------------------------------------------|------------------------|-------------------------------------------------|--------|----------------------------------|----------------|
| L-Awstrija          | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria                | Ežomeprażol manjeżju   | Neximyl 40 mg magsensafresistente Hartkapseln   | 40 mg  | Kapsula gastro-reżistenti, iebša | Użu orali      |
| L-Awstrija          | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria                | Kandesartan ċileksetil | Candesartan Arcana 4 mg Tabletten               | 4 mg   | Pillola                          | Użu orali      |
| L-Awstrija          | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria                | Kandesartan ċileksetil | Candesartan Arcana 8 mg Tabletten               | 8 mg   | Pillola                          | Użu orali      |
| L-Awstrija          | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria                | Kandesartan ċileksetil | Candesartan Arcana 16 mg Tabletten              | 16 mg  | Pillola                          | Użu orali      |
| L-Awstrija          | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria                | Kandesartan ċileksetil | Candesartan Arcana 32 mg Tabletten              | 32 mg  | Pillola                          | Użu orali      |
| L-Awstrija          | Genericon Pharma GmbH<br>Hafnerstr. 211<br>8054 Graz<br>Austria                             | Nebivolol              | Nebivolol Genericon 5 mg Tabletten              | 5 mg   | Pillola                          | Użu orali      |
| L-Awstrija          | Ratiopharm Arzneimittel-Vertriebs-GmbH<br>Albert-Schweitzer-Gasse 3<br>1140 Wien<br>Austria | Desloratadina          | Desloratadin ratiopharm 2,5 mg Schmelztabletten | 2,5 mg | Pillola li tinħall fil-ħalq      | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                        | INN           | Isem l-vintat                                 | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|---------------------|---------------------------------------------------------------------------------------------|---------------|-----------------------------------------------|--------|-----------------------------|----------------|
| L-Awstrija          | Ratiopharm Arzneimittel-Vertriebs-GmbH<br>Albert-Schweitzer-Gasse 3<br>1140 Wien<br>Austria | Desloratadina | Desloratadin ratiopharm 5 mg Schmelztabletten | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| Il-Belġju           | Apotex Europe B.V.<br>Darwinweg 20<br>NL 2333 CR Leiden<br>Netherlands                      | Desloratadina | Desloratadine Apotex                          | 5 mg   | Pillola miksjia b'rita      | Użu orali      |
| Il-Belġju           | Mylan bvba/sprl<br>Terhulpsesteenweg 6 A<br>1560 Hoeilaart<br>Belgium                       | Donepezil     | Donepezil Odis Mylan                          | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| Il-Belġju           | Mylan bvba/sprl<br>Terhulpsesteenweg 6 A<br>1560 Hoeilaart<br>Belgium                       | Donepezil     | Donepezil Odis Mylan                          | 10 mg  | Pillola li tinħall fil-halq | Użu orali      |
| Il-Belġju           | Mylan bvba/sprl<br>Terhulpsesteenweg 6 A<br>1560 Hoeilaart<br>Belgium                       | Repaglinid    | Repaglinide Mylan 0,5 mg Pharma               | 0,5 mg | Pillola                     | Użu orali      |
| Il-Belġju           | Mylan bvba/sprl<br>Terhulpsesteenweg 6 A<br>1560 Hoeilaart<br>Belgium                       | Repaglinid    | Repaglinide Mylan 1 mg Pharma                 | 1 mg   | Pillola                     | Użu orali      |
| Il-Belġju           | Mylan bvba/sprl<br>Terhulpsesteenweg 6 A<br>1560 Hoeilaart<br>Belgium                       | Repaglinid    | Repaglinide Mylan 2 mg Pharma                 | 2 mg   | Pillola                     | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                 | INN               | Isem l-vintat      | Qawwa  | Għamla farmaċewtika              | Mnejn jingħata |
|---------------------|----------------------------------------------------------------------|-------------------|--------------------|--------|----------------------------------|----------------|
| Il-Belġju           | Mylan bvba/sprl<br>Terhulpssteenweg 6 A<br>1560 Hoeilaart<br>Belgium | Kandesartan       | Candesartan Mylan  | 8 mg   | Pillola                          | Użu orali      |
| Il-Belġju           | Mylan bvba/sprl<br>Terhulpssteenweg 6 A<br>1560 Hoeilaart<br>Belgium | Kandesartan       | Candesartan Mylan  | 16 mg  | Pillola                          | Użu orali      |
| Il-Belġju           | Mylan bvba/sprl<br>Terhulpssteenweg 6 A<br>1560 Hoeilaart<br>Belgium | Kandesartan       | Candesartan Mylan  | 32 mg  | Pillola                          | Użu orali      |
| Il-Belġju           | Mylan bvba/sprl<br>Terhulpssteenweg 6 A<br>1560 Hoeilaart<br>Belgium | Ezomeprazol       | Esomeprazole Mylan | 20 mg  | Kapsula gastro-reżistenti, iebsa | Użu orali      |
| Il-Belġju           | Mylan bvba/sprl<br>Terhulpssteenweg 6 A<br>1560 Hoeilaart<br>Belgium | Ezomeprazol       | Esomeprazole Mylan | 40 mg  | Kapsula gastro-reżistenti, iebsa | Użu orali      |
| Il-Belġju           | Takeda Belgium<br>Gentsesteenweg 615<br>1080 Brussels<br>Belgium     | Acidu alendroniku | Alendromono        | 70 mg  | Pillola                          | Użu orali      |
| Il-Belġju           | Teva Pharma Belgium NV<br>Laarstraat 16<br>2610 Wilrijk<br>Belgium   | Desloratadina     | Desloratadine Teva | 2,5 mg | Pillola li tinħall fil-halq      | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                            | INN           | Isem Ivvintat      | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------------------------------------|---------------|--------------------|--------|-----------------------------|----------------|
| Il-Belġju            | Teva Pharma Belgium NV<br>Laarstraat 16<br>2610 Wilrijk<br>Belgium                                              | Desloratadina | Desloratadine Teva | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| Il-Bulgarija         | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol     | Ropinirole Accord  | 0,5 mg | Pillola miksjja b'rita      | Użu orali      |
| Il-Bulgarija         | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol     | Ropinirole Accord  | 1 mg   | Pillola miksjja b'rita      | Użu orali      |
| Il-Bulgarija         | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol     | Ropinirole Accord  | 2 mg   | Pillola miksjja b'rita      | Użu orali      |
| Il-Bulgarija         | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol     | Ropinirole Accord  | 5 mg   | Pillola miksjja b'rita      | Użu orali      |
| Il-Bulgarija         | Alkaloid – INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana – Črnuče<br>Slovenia                                     | Čeľpodoksima  | FOXERO             | 200 mg | Pillola                     | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                        | INN                  | Isem Ivvintat                             | Qawwa  | Għamla farmaċewtika                  | Mnejn jingħata |
|---------------------|---------------------------------------------------------------------------------------------|----------------------|-------------------------------------------|--------|--------------------------------------|----------------|
| Il-Bulgarija        | Aquachim AD<br>blvd. Prof. Tsvetan Lazarov 83<br>Sofia 1582<br>Bulgaria                     | Ketjapina            | Aquatiapine                               | 25 mg  | Pillola miksija b'rita               | Użu orali      |
| Il-Bulgarija        | Aquachim AD<br>blvd. Prof. Tsvetan Lazarov 83<br>Sofia 1582<br>Bulgaria                     | Ketjapina            | Aquatiapine                               | 100 mg | Pillola miksija b'rita               | Użu orali      |
| Il-Bulgarija        | Aquachim AD<br>blvd. Prof. Tsvetan Lazarov 83<br>Sofia 1582<br>Bulgaria                     | Ketjapina            | Aquatiapine                               | 200 mg | Pillola miksija b'rita               | Użu orali      |
| Il-Bulgarija        | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Ezomeprazol manjeżju | Esopragen                                 | 20 mg  | Kapsula gastro-reżistenti, iebsa     | Użu orali      |
| Il-Bulgarija        | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Ezomeprazol manjeżju | Esopragen                                 | 40 mg  | Kapsula gastro-reżistenti, iebsa     | Użu orali      |
| Il-Bulgarija        | Glenmark Pharmaceuticals s.r.o.<br>Hvězdova 1716/2b<br>14078 Praha 4<br>Czech Republic      | Trimetazidina        | Apstar 35 mg<br>prolonged-release tablets | 35 mg  | Pillola li terhi il-medicina bil-mod | Użu orali      |
| Il-Bulgarija        | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                      | Trimetazidina        | Trimetazigen MR                           | 35 mg  | Pillola li terhi il-medicina bil-mod | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                    | INN           | Isem l-vintat                              | Qawwa   | Għamla farmaċewtika                  | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------------|---------------|--------------------------------------------|---------|--------------------------------------|----------------|
| Il-Bulgarija        | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia           | Trimetazidina | Energotrim                                 | 35 mg   | Pillola li terhi il-mediċina bil-mod | Użu orali      |
| Il-Bulgarija        | Tchaikapharma Highquality Medicines<br>1 G. M. Dimitrov Blvd.<br>Sofia 1172<br>Bulgaria | Bosentan      | Pulmohyperta                               | 62,5 mg | Pillola miksjia b'rita               | Użu orali      |
| Il-Bulgarija        | Tchaikapharma Highquality Medicines<br>1 G. M. Dimitrov Blvd.<br>Sofia 1172<br>Bulgaria | Bosentan      | Pulmohyperta                               | 125 mg  | Pillola miksjia b'rita               | Użu orali      |
| Il-Kroazja          | Alkaloid d.o.o.<br>Ulica grada Vukovara 226 F<br>Zagreb 10000<br>Croatia                | Čefpodoksima  | Rexocef 200 mg filmom obložene tablete     | 200 mg  | Pillola miksjia b'rita               | Użu orali      |
| Il-Kroazja          | Belupo, lijekovi i kozmetika d.d.<br>Ulica Danica 5<br>Koprivnica 48000<br>Croatia      | Desloratadina | Alerdin 2,5 mg raspadljive tablete za usta | 2,5 mg  | Pillola li tinħall fil-ħalq          | Użu orali      |
| Il-Kroazja          | Belupo, lijekovi i kozmetika d.d.<br>Ulica Danica 5<br>Koprivnica 48000<br>Croatia      | Desloratadina | Alerdin 5 mg raspadljive tablete za usta   | 5 mg    | Pillola li tinħall fil-ħalq          | Użu orali      |
| Il-Kroazja          | Fidifarm d.o.o.<br>Obrtnička 37, Bestovje<br>Rakitje 10437<br>Croatia                   | Desloratadina | Sinalerg 5 mg filmom obložene tablete      | 5 mg    | Pillola miksjia b'rita               | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                            | INN                    | Isem l-vintat                                                              | Qawwa          | Għamla farmaċewtika                       | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------------------------------------|------------------------|----------------------------------------------------------------------------|----------------|-------------------------------------------|----------------|
| Il-Kroazja          | Jadran Galenski Laboratorij d.d.<br>Svilno 20, Rijeka<br>51 000<br>Croatia                                      | Desloratadina          | Escontral direkt 2,5 mg raspadljiva<br>tableta za usta                     | 2,5 mg         | Pillola li tinħall fil-halq               | Użu orali      |
| Il-Kroazja          | Jadran Galenski Laboratorij d.d.<br>Svilno 20, Rijeka<br>51 000<br>Croatia                                      | Desloratadina          | Escontral direkt 5 mg raspadljiva<br>tableta za usta                       | 5 mg           | Pillola li tinħall fil-halq               | Użu orali      |
| Il-Kroazja          | PharmaS d.o.o.<br>Radnička cesta 47<br>Zagreb 10000<br>Croatia                                                  | Tramadol/paracetamol   | Tramadol/Paracetamol PharmaS<br>37,5 mg/<br>325 mg filmom obložene tablete | 37,5 mg/325 mg | Pillola miksija b'rita                    | Użu orali      |
| Il-Kroazja          | PharmaS d.o.o.<br>Radnička cesta 47<br>Zagreb 10000<br>Croatia                                                  | Exxitalopram           | Escitalopram PharmaS 10 mg fil-<br>mom<br>obložene tablete                 | 10 mg          | Pillola miksija b'rita                    | Użu orali      |
| Il-Kroazja          | Sandoz d.o.o.<br>Maksimirska 120<br>Zagreb 10000<br>Croatia                                                     | Trimetazidina kloridra | Vazidin 35 mg tablete s produljenim<br>oslobađanjem                        | 35 mg          | Pillola li terhi il-medi-<br>cina bil-mod | Użu orali      |
| Ċipru               | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Acidu alendroniku      | Alendronic Acid Accord                                                     | 70 mg          | Pillola                                   | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                                                      | INN                             | Isem Ivvintat           | Qawwa          | Għamla farmaċewtika         | Mnejn jingħata |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------|----------------|-----------------------------|----------------|
| Ċipru               | Delorbis Pharmaceuticals Ltd<br>17 Athinon Street<br>Ergates Industrial Area<br>2643 Ergates<br>P.O. Box 28629<br>2081 Lefkosia<br>Cyprus | Ertakapon                       | Nobat                   | 200 mg         | Pillola miksija b'rita      | Użu orali      |
| Ċipru               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                                               | Valsartan/idrokloroti-<br>jażid | Valsartan/Hctz Fair-med | 160 mg/12,5 mg | Pillola miksija b'rita      | Użu orali      |
| Ċipru               | Generics Pharma Hellas Ltd<br>577a Vouliagmenis Avenue<br>Argyroupoli<br>164-51 Athens<br>Greece                                          | Donepezil kloridrat             | Donepezil/Generics      | 5 mg           | Pillola li tinħall fil-halq | Użu orali      |
| Ċipru               | Generics Pharma Hellas Ltd<br>577a Vouliagmenis Avenue<br>Argyroupoli<br>164-51 Athens<br>Greece                                          | Donepezil kloridrat             | Donepezil/Generics      | 10 mg          | Pillola li tinħall fil-halq | Użu orali      |
| Ċipru               | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North Harrow<br>Middlesex HA1 4HF<br>United Kingdom                          | Ropinirol kloridrat             | Ropinirole Lambda       | 0,25 mg        | Pillola miksija b'rita      | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                             | INN                    | Isem Ivvintat         | Qawwa  | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|------------------------------------------------------------------------------------------------------------------|------------------------|-----------------------|--------|------------------------|----------------|
| Ċipru               | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirol kloridrat    | Ropinirole Lambda     | 0,5 mg | Pillola miksija b'rita | Użu orali      |
| Ċipru               | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirol kloridrat    | Ropinirole Lambda     | 1 mg   | Pillola miksija b'rita | Użu orali      |
| Ċipru               | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirol kloridrat    | Ropinirole Lambda     | 2 mg   | Pillola miksija b'rita | Użu orali      |
| Ċipru               | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirol kloridrat    | Ropinirole Lambda     | 5 mg   | Pillola miksija b'rita | Użu orali      |
| Ċipru               | Wockhardt UK Limited<br>Ash Road North<br>Wrexham Industrial Estate<br>Wrexham LL13 9UF<br>United Kingdom        | Klopidoogrel kloridrat | Clopidogrel/Wockhardt | 75 mg  | Pillola miksija b'rita | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                        | INN                           | Isem l-vintat                   | Qawwa  | Għamla farmaċewtika                       | Mnejn jingħata |
|---------------------|-------------------------------------------------------------------------------------------------------------|-------------------------------|---------------------------------|--------|-------------------------------------------|----------------|
| Ir-Repubblika Ċeka  | Abbott Laboratories, s.r.o.<br>Evropská 2591/33d<br>160 00 Praha 6 – Hradovka Office Park<br>Czech Republic | Ossalat tal-exxitalo-<br>pram | Purcema 5 mg                    | 5 mg   | Pillola miksija b'rita                    | Użu orali      |
| Ir-Repubblika Ċeka  | Abbott Laboratories, s.r.o.<br>Evropská 2591/33d<br>160 00 Praha 6 – Hradovka Office Park<br>Czech Republic | Ossalat tal-exxitalo-<br>pram | Purcema 10 mg                   | 10 mg  | Pillola miksija b'rita                    | Użu orali      |
| Ir-Repubblika Ċeka  | Abbott Laboratories, s.r.o.<br>Evropská 2591/33d<br>160 00 Praha 6 – Hradovka Office Park<br>Czech Republic | Ossalat tal-exxitalo-<br>pram | Purcema 15 mg                   | 15 mg  | Pillola miksija b'rita                    | Użu orali      |
| Ir-Repubblika Ċeka  | Abbott Laboratories, s.r.o.<br>Evropská 2591/33d<br>160 00 Praha 6 – Hradovka Office Park<br>Czech Republic | Ossalat tal-exxitalo-<br>pram | Purcema 20 mg                   | 20 mg  | Pillola miksija b'rita                    | Użu orali      |
| Ir-Repubblika Ċeka  | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland                             | Metformina kloridrata         | Metformin Actavis Retard 500 mg | 500 mg | Pillola li terhi il-medi-<br>ċina bil-mod | Użu orali      |
| Ir-Repubblika Ċeka  | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland                             | Metformina kloridrata         | Metformin Actavis Retard 750 mg | 750 mg | Pillola li terhi il-medi-<br>ċina bil-mod | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                        | INN                        | Isem Ivvintat                                | Qawwa  | Għamla farmaċewtika                  | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------------------|----------------------------|----------------------------------------------|--------|--------------------------------------|----------------|
| Ir-Repubblika Ċeka   | Alkaloid – INT d.o.o.<br>Štandrova 4<br>1231 Ljubljana – Črnuče<br>Slovenia                 | Ċefpodoksima               | Forexo 200 mg potahované tablety             | 200 mg | Pillola miksija b'rita               | Użu orali      |
| Ir-Repubblika Ċeka   | Alvogen IPCo S.r.l.<br>Rue Heienhaff 5<br>L-1736 Senningerberg<br>Lussemburgu               | Desloratadina              | Desloratadin Alvogen 5 mg potahované tablety | 5 mg   | Pillola miksija b'rita               | Użu orali      |
| Ir-Repubblika Ċeka   | Apotex Europe B.V.<br>Darwinweg 20<br>NL 2333 CR Leiden<br>Netherlands                      | Trimetazidina dikloridrata | Apo-trimetazidin 35 mg                       | 35 mg  | Pillola li terhi il-medicina bil-mod | Użu orali      |
| Ir-Repubblika Ċeka   | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Ežomeprazol manježju       | Esomylan 40 mg                               | 40 mg  | Kapsula gastro-režistenti, iebsa     | Użu orali      |
| Ir-Repubblika Ċeka   | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Benžoat tar-rizatriptan    | Rizatriptan Mylan 5 mg                       | 5 mg   | Pillola li tinħall fil-halq          | Użu orali      |
| Ir-Repubblika Ċeka   | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Benžoat tar-rizatriptan    | Rizatriptan Mylan 10 mg                      | 10 mg  | Pillola li tinħall fil-halq          | Użu orali      |
| Ir-Repubblika Ċeka   | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezil kloridrat        | Donepezil Mylan 10 mg                        | 10 mg  | Pillola li tinħall fil-halq          | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                      | INN                        | Isem Ivvintat                                                 | Qawwa  | Għamla farmaċewtika                  | Mnejn jingħata |
|----------------------|-------------------------------------------------------------------------------------------|----------------------------|---------------------------------------------------------------|--------|--------------------------------------|----------------|
| Ir-Repubblika Ċeka   | Glenmark Pharmaceuticals s.r.o.<br>Hvězdova 1716/2b<br>14078 Praha 4<br>Czech Republic    | Trimetazidina dikloridrata | Portora 35 mg tablety s prodlouženým uvolňováním              | 35 mg  | Pillola li terhi il-mediċina bil-mod | Użu orali      |
| Ir-Repubblika Ċeka   | GNR Czech s.r.o.<br>Slavojova 579/9<br>128 00 Praha 2<br>Czech Republic                   | Desloratadina              | Geslora 5 mg                                                  | 5 mg   | Pillola miksija b'rita               | Użu orali      |
| Ir-Repubblika Ċeka   | Labormed-Pharma, SA<br>Theodor Pallady, 44B<br>032266 Bucharest<br>Romania                | Desloratadina              | Desloratadin Labormed 2,5 mg tablety dispergovatelne v ústech | 2,5 mg | Pillola li tinħall fil-ħalq          | Użu orali      |
| Ir-Repubblika Ċeka   | Labormed-Pharma, SA<br>Theodor Pallady, 44B<br>032266 Bucharest<br>Romania                | Desloratadina              | Desloratadin Labormed 5 mg tablety dispergovatelne v ústech   | 5 mg   | Pillola li tinħall fil-ħalq          | Użu orali      |
| Ir-Repubblika Ċeka   | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                    | Trimetazidina              | Trimetazidin Mylan 35 mg                                      | 35 mg  | Pillola li terhi il-mediċina bil-mod | Użu orali      |
| Ir-Repubblika Ċeka   | SVUS Pharma a.s.<br>Smetanovo nábřeží 1238/20a<br>500 02 Hradec Králové<br>Czech Republic | Desloratadina              | Lotera 5 mg potahované tablety                                | 5 mg   | Pillola miksija b'rita               | Użu orali      |
| Id-Danimarka         | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland           | Metformina                 | Metformin "Actavis PTC"                                       | 500 mg | Pillola li terhi il-mediċina bil-mod | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                            | INN                             | Isem Ivvintat                              | Qawwa          | Għamla farmaċewtika                       | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------|---------------------------------|--------------------------------------------|----------------|-------------------------------------------|----------------|
| Id-Danimarka         | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland | Metformina                      | Metformin "Actavis PTC"                    | 750 mg         | Pillola li terhi il-medi-<br>ċina bil-mod | Użu orali      |
| Id-Danimarka         | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden     | Flukonazol                      | Fluconazol "Bluefish"                      | 50 mg          | Kapsula, iebsa                            | Użu orali      |
| Id-Danimarka         | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden     | Flukonazol                      | Fluconazol "Bluefish"                      | 150 mg         | Kapsula, iebsa                            | Użu orali      |
| Id-Danimarka         | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden     | Flukonazol                      | Fluconazol "Bluefish"                      | 200 mg         | Kapsula, iebsa                            | Użu orali      |
| Id-Danimarka         | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany     | Valsartan/idrokloroti-<br>jazid | Valsartan/hydrochlorthiazid "Fair-<br>Med" | 160 mg/12,5 mg | Pillola miksiġa b'rita                    | Użu orali      |
| Id-Danimarka         | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany     | Valsartan/idrokloroti-<br>jazid | Valsartan/hydrochlorthiazid "Fair-<br>Med" | 320 mg/12,5 mg | Pillola miksiġa b'rita                    | Użu orali      |
| Id-Danimarka         | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany     | Valsartan/idrokloroti-<br>jazid | Valsartan/hydrochlorthiazid "Fair-<br>Med" | 320 mg/25 mg   | Pillola miksiġa b'rita                    | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                            | INN               | Isem Ivvintat                   | Qawwa  | Għamla farmaċewtika                          | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------------------------------------|-------------------|---------------------------------|--------|----------------------------------------------|----------------|
| Id-Danimarka         | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                                      | Eletriptan        | Eletriptan Mylan                | 40 mg  | Pillola miksija b'rita                       | Użu orali      |
| Id-Danimarka         | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                                      | Ežomeprazol       | Esomeprazol Mylan               | 20 mg  | Kapsula gastro-reżistenti, iebsa             | Użu orali      |
| Id-Danimarka         | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                                      | Ežomeprazol       | Esomeprazol Mylan               | 40 mg  | Kapsula gastro-reżistenti, iebsa             | Użu orali      |
| Id-Danimarka         | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                                      | Rizatriptan       | Rizatriptan Mylan               | 10 mg  | Pillola li tinħall fil-halq                  | Użu orali      |
| Id-Danimarka         | Stadapharm GmbH<br>Stadastr. 2-18<br>D-61118 Bad Vilbel<br>Germany                                              | Entakapon         | Entacapon STADA                 | 200 mg | Pillola miksija b'rita                       | Użu orali      |
| L-Estonja            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Acidu alendroniku | ALENDRONIC ACID ACCORD<br>70 mg | 70 mg  | Pillola                                      | Użu orali      |
| L-Estonja            | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia                                   | Trimetazidina     | ZIDMETIN                        | 35 mg  | Pillola li terhi il-medicina b'mod modifikat | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                            | INN        | Isem Ivvintat       | Qawwa  | Għamla farmaċewtika                       | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------|------------|---------------------|--------|-------------------------------------------|----------------|
| Il-Finlandja         | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland | Metformina | Metformin Actavis   | 500 mg | Pillola li terhi il-medi-<br>ċina bil-mod | Użu orali      |
| Il-Finlandja         | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland | Metformina | Metformin Actavis   | 750 mg | Pillola li terhi il-medi-<br>ċina bil-mod | Użu orali      |
| Il-Finlandja         | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden     | Flukonazol | Fluconazol Bluefish | 50 mg  | Kapsula, iebsa                            | Użu orali      |
| Il-Finlandja         | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden     | Flukonazol | Fluconazol Bluefish | 150 mg | Kapsula, iebsa                            | Użu orali      |
| Il-Finlandja         | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden     | Flukonazol | Fluconazol Bluefish | 200 mg | Kapsula, iebsa                            | Użu orali      |
| Il-Finlandja         | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                      | Eletriptan | Eletriptan Mylan    | 40 mg  | Pillola miksija b'rita                    | Użu orali      |
| Il-Finlandja         | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                      | Repaglinid | Repaglinid Mylan    | 0,5 mg | Pillola                                   | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                     | INN        | Isem Ivvintat    | Qawwa  | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|--------------------------------------------------------------------------|------------|------------------|--------|------------------------|----------------|
| Il-Finlandja        | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden               | Repaglinid | Repaglinid Mylan | 1 mg   | Pillola                | Użu orali      |
| Il-Finlandja        | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden               | Repaglinid | Repaglinid Mylan | 2 mg   | Pillola                | Użu orali      |
| Il-Finlandja        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland | Valsartan  | VALSARTAN ORION  | 40 mg  | Pillola miksija b'rita | Użu orali      |
| Il-Finlandja        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland | Valsartan  | VALSARTAN ORION  | 80 mg  | Pillola miksija b'rita | Użu orali      |
| Il-Finlandja        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland | Valsartan  | VALSARTAN ORION  | 160 mg | Pillola miksija b'rita | Użu orali      |
| Il-Finlandja        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland | Valsartan  | VALSARTAN ORION  | 320 mg | Pillola miksija b'rita | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                              | INN           | Isem Ivvintat                                 | Qawwa   | Għamla farmaċewtika         | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------|---------------|-----------------------------------------------|---------|-----------------------------|----------------|
| Il-Finlandja         | Ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>D-89079 Ulm<br>Germany                  | Desloratadina | Desloratadine Ratiopharm                      | 2,5 mg  | Pillola li tinħall fil-halq | Użu orali      |
| Il-Finlandja         | Ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>D-89079 Ulm<br>Germany                  | Desloratadina | Desloratadine Ratiopharm                      | 5 mg    | Pillola li tinħall fil-halq | Użu orali      |
| Franza               | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France         | Exxitalopram  | ESCITALOPRAM ABBOTT 5 mg, comprimé pelliculé  | 5 mg    | Pillola miksjia b'rita      | Użu orali      |
| Franza               | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France         | Exxitalopram  | ESCITALOPRAM ABBOTT 10 mg, comprimé pelliculé | 10 mg   | Pillola miksjia b'rita      | Użu orali      |
| Franza               | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France         | Exxitalopram  | ESCITALOPRAM ABBOTT 15 mg, comprimé pelliculé | 15 mg   | Pillola miksjia b'rita      | Użu orali      |
| Franza               | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France         | Exxitalopram  | ESCITALOPRAM ABBOTT 20 mg, comprimé pelliculé | 20 mg   | Pillola miksjia b'rita      | Użu orali      |
| Franza               | ACCORD HEALTHCARE France SAS<br>45 Rue de Fbg de Roubaix<br>59000 Lille<br>France | Ropinirol     | Ropinirole Accord 0,25 mg, comprimé pelliculé | 0,25 mg | Pillola miksjia b'rita      | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                        | INN          | Isem Ivvintat                                           | Qawwa  | Għamla farmaċewtika     | Mnejn jingħata |
|---------------------|---------------------------------------------------------------------------------------------|--------------|---------------------------------------------------------|--------|-------------------------|----------------|
| Franza              | ACCORD HEALTHCARE France SAS<br>45 Rue de Fbg de Roubaix<br>59000 Lille<br>France           | Ropinirol    | Ropinirole Accord 0,5 mg, comprimé<br>mé pelliculé      | 0,5 mg | Pillola miksjija b'rita | Użu orali      |
| Franza              | ACCORD HEALTHCARE France SAS<br>45 Rue de Fbg de Roubaix<br>59000 Lille<br>France           | Ropinirol    | Ropinirole Accord 1 mg, comprimé<br>pelliculé           | 1 mg   | Pillola miksjija b'rita | Użu orali      |
| Franza              | ACCORD HEALTHCARE France SAS<br>45 Rue de Fbg de Roubaix<br>59000 Lille<br>France           | Ropinirol    | Ropinirole Accord 2 mg, comprimé<br>pelliculé           | 2 mg   | Pillola miksjija b'rita | Użu orali      |
| Franza              | ACCORD HEALTHCARE France SAS<br>45 Rue de Fbg de Roubaix<br>59000 Lille<br>France           | Ropinirol    | Ropinirole Accord 5 mg, comprimé<br>pelliculé           | 5 mg   | Pillola miksjija b'rita | Użu orali      |
| Franza              | Brown & Burk UK, Ltd.<br>5, Maryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Exxitalopram | ESCITALOPRAM BROWN 5 mg,<br>comprimé pelliculé sécable  | 5 mg   | Pillola miksjija b'rita | Użu orali      |
| Franza              | Brown & Burk UK, Ltd.<br>5, Maryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Exxitalopram | ESCITALOPRAM BROWN 10 mg,<br>comprimé pelliculé sécable | 10 mg  | Pillola miksjija b'rita | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                         | INN           | Isem Ivvinat                                            | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|---------------------|----------------------------------------------------------------------------------------------|---------------|---------------------------------------------------------|--------|-----------------------------|----------------|
| Franza              | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Exxitalopram  | ESCITALOPRAM BROWN 15 mg,<br>comprimé pelliculé sécable | 15 mg  | Pillola miksija b'rita      | Użu orali      |
| Franza              | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Exxitalopram  | ESCITALOPRAM BROWN 20 mg,<br>comprimé pelliculé sécable | 20 mg  | Pillola miksija b'rita      | Użu orali      |
| Franza              | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Ebastina      | EBASTINE BROWN & BURK<br>10 mg, comprimé orodispersible | 10 mg  | Pillola li tinħall fil-halq | Użu orali      |
| Franza              | Cristers<br>22, quai Galliéni<br>92150 Suresnes<br>France                                    | Desloratadina | DESLOTATADINE CRISTERS<br>5 mg<br>comprimé pelliculé    | 5 mg   | Pillola miksija b'rita      | Użu orali      |
| Franza              | Cristers<br>22, quai Galliéni<br>92150 Suresnes<br>France                                    | Ibuprofen     | IBUPROFENE CRISTERS<br>400 mg<br>comprimé pelliculé     | 400 mg | Pillola miksija b'rita      | Użu orali      |
| Franza              | Laboratoires Biogaran<br>15, boulevard Charles de Gaulle<br>92707 Colombes Cedex<br>France   | Ebastina      | EBASTINE BIOGARAN 10 mg<br>comprimé pelliculé           | 10 mg  | Pillola miksija b'rita      | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                     | INN                  | Isem Ivvintat                                                         | Qawwa          | Għamla farmaċewtika         | Mnejn jingħata |
|---------------------|----------------------------------------------------------------------------------------------------------|----------------------|-----------------------------------------------------------------------|----------------|-----------------------------|----------------|
| Franza              | Laboratoires Biogaran<br>15, boulevard Charles de Gaulle<br>92707 Colombes Cedex<br>France               | Ebastina             | EBASTINE BIOGARAN 10 mg<br>comprimé orodispersible                    | 10 mg          | Pillola li tinħall fil-halq | Użu orali      |
| Franza              | Laboratoires GERDA<br>24 rue Erlanger<br>75016 PARIS<br>France                                           | Desloratadina        | DESLOTATADINE ARROW<br>5 mg<br>comprimé pelliculé                     | 5 mg           | Pillola miksiġa b'rita      | Użu orali      |
| Franza              | Medipha Sante<br>Les Fjords – Immeuble Oslo<br>19 avenue de Norvège<br>91953 Courtaboeuf Cedex<br>France | Tramadol/paracétamol | TRAMADOL PARACETAMOL NIA-<br>LEX 37,5 mg/325 mg comprimé<br>pelliculé | 37,5 mg/325 mg | Pillola miksiġa b'rita      | Użu orali      |
| Franza              | Medipha Sante<br>Les Fjords – Immeuble Oslo<br>19 avenue de Norvège<br>91953 Courtaboeuf Cedex<br>France | Desloratadina        | DESLOTATADINE GNR<br>5 mg<br>comprimé pelliculé                       | 5 mg           | Pillola miksiġa b'rita      | Użu orali      |
| Franza              | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                                   | Rizatriptan          | RIZATRIPTAN MYLAN 5 mg, oro-<br>dispersible tablet                    | 5 mg           | Pillola li tinħall fil-halq | Użu orali      |
| Franza              | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                                   | Rizatriptan          | RIZATRIPTAN MYLAN 10 mg,<br>orodispersible tablet                     | 10 mg          | Pillola li tinħall fil-halq | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                   | INN           | Isem Ivvintat                                      | Qawwa | Għamla farmaċewtika                          | Mnejn jingħata |
|----------------------|------------------------------------------------------------------------|---------------|----------------------------------------------------|-------|----------------------------------------------|----------------|
| Franza               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Ebastina      | EBASTINE MYLAN 10 mg, film-coated tablet           | 10 mg | Pillola miksija b'rita                       | Użu orali      |
| Franza               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Ebastina      | EBASTINE MYLAN 10 mg, orodispersible tablet        | 10 mg | Pillola li tinhall fil-halq                  | Użu orali      |
| Franza               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Trimetazidina | TRIMETAZIDINE MYLAN 35 mg Modified Release Tablets | 35 mg | Pillola li terhi il-mediċina b'mod modifikat | Użu orali      |
| Franza               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Kandesartan   | CANDESARTAN MYLAN 32 mg, comprimé sécable          | 32 mg | Pillola                                      | Użu orali      |
| Franza               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Donepezil     | DONEPEZIL MYLAN 5 mg, orodispersible tablet        | 5 mg  | Pillola li tinhall fil-halq                  | Użu orali      |
| Franza               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Donepezil     | DONEPEZIL MYLAN 10 mg, orodispersible tablet       | 10 mg | Pillola li tinhall fil-halq                  | Użu orali      |
| Franza               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Ezomeprazol   | ESOMEPRAZOLE MYLAN PHARMA 20 mg, DR capsule        | 20 mg | Kapsula gastro-reżistenti, iebša             | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                              | INN           | Isem Ivvintat                                     | Qawwa   | Għamla farmaċewtika              | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------|---------------|---------------------------------------------------|---------|----------------------------------|----------------|
| Franza              | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France            | Ezomeprazol   | ESOMEPRAZOLE MYLAN PHARMA 40 mg, DR capsule       | 40 mg   | Kapsula gastro-reżistenti, iebsa | Użu orali      |
| Franza              | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France            | Desmopressina | DESMOPRESSINE MYLAN 60 µg, orodispersible tablet  | 0,06 mg | Pillola li tinħall fil-halq      | Użu orali      |
| Franza              | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France            | Desmopressina | DESMOPRESSINE MYLAN 120 µg, orodispersible tablet | 0,12 mg | Pillola li tinħall fil-halq      | Użu orali      |
| Franza              | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France            | Desmopressina | DESMOPRESSINE MYLAN 240 µg, orodispersible tablet | 0,24 mg | Pillola li tinħall fil-halq      | Użu orali      |
| Franza              | Ranbaxy Pharmacie Generiques<br>11-15 Quai Dion Bouton<br>92800 Puteaux<br>France | Aciklovir     | Aciclovir Ranbaxy 800 mg, comprimé                | 800 mg  | Pillola                          | Użu orali      |
| Franza              | Ranbaxy Pharmacie Generiques<br>11-15 Quai Dion Bouton<br>92800 Puteaux<br>France | Aciklovir     | Aciclovir Ranbaxy 200 mg, comprimé                | 200 mg  | Pillola                          | Użu orali      |
| Franza              | Ranbaxy Pharmacie Generiques<br>11-15 Quai Dion Bouton<br>92800 Puteaux<br>France | Aciklovir     | Aciclovir Almus 200 mg, comprimé                  | 200 mg  | Pillola                          | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                       | INN               | Isem l-vintat                                       | Qawwa | Għamla farmaċewtika         | Mnejn jingħata |
|---------------------|------------------------------------------------------------------------------------------------------------|-------------------|-----------------------------------------------------|-------|-----------------------------|----------------|
| Franza              | Ranbaxy Pharmacie Generiques<br>11-15 Quai Dion Bouton<br>92800 Puteaux<br>France                          | Acidu alendroniku | Acide Alendronique Ranbaxy<br>70 mg, comprimé       | 70 mg | Pillola                     | Użu orali      |
| Franza              | Sanofi Aventis France<br>1-13 bd Romain Rolland<br>75159 Paris Cedex 14<br>France                          | Ebastina          | EBASTINE ZENTIVA 10 mg comprimé pelliculé           | 10 mg | Pillola miksjija b'rita     | Użu orali      |
| Franza              | Sanofi Aventis France<br>1-13 bd Romain Rolland<br>75159 Paris Cedex 14<br>France                          | Ebastina          | EBASTINE ZENTIVA 10 mg comprimé orodispersible      | 10 mg | Pillola li tinħall fil-halq | Użu orali      |
| Franza              | Teva Sante<br>Cœur Défense – 100-110<br>Esplanade du Général de Gaulle<br>92931 La Défense Cedex<br>France | Desloratadina     | DESLOTATADINE TEVA SANTE<br>5 mg comprimé pelliculé | 5 mg  | Pillola miksjija b'rita     | Użu orali      |
| Franza              | Venipharm SAS<br>4 Bureaux de la Colline<br>92213 Saint-Cloud<br>France                                    | Ebastina          | EBOUDA 10 mg comprimé pelliculé                     | 10 mg | Pillola miksjija b'rita     | Użu orali      |
| Franza              | Venipharm SAS<br>4 Bureaux de la Colline<br>92213 Saint-Cloud<br>France                                    | Ebastina          | EBARREN 10 mg comprimé pelliculé                    | 10 mg | Pillola miksjija b'rita     | Użu orali      |
| Franza              | Venipharm SAS<br>4 Bureaux de la Colline<br>92213 Saint-Cloud<br>France                                    | Ebastina          | EBONDE 10 mg comprimé pelliculé                     | 10 mg | Pillola miksjija b'rita     | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                            | INN                  | Isem Ivvintat                                                       | Qawwa          | Għamla farmaċewtika         | Mnejn jingħata |
|---------------------|-------------------------------------------------------------------------------------------------|----------------------|---------------------------------------------------------------------|----------------|-----------------------------|----------------|
| Franza              | Venipharm SAS<br>4 Bureaux de la Colline<br>92213 Saint-Cloud<br>France                         | Ebastina             | EBONTAN 10 mg comprimé oro-dispersible                              | 10 mg          | Pillola li tinhall fil-halq | Użu orali      |
| Franza              | Venipharm SAS<br>4 Bureaux de la Colline<br>92213 Saint-Cloud<br>France                         | Ebastina             | EBACHOI 10 mg comprimé oro-dispersible                              | 10 mg          | Pillola li tinhall fil-halq | Użu orali      |
| Franza              | Venipharm SAS<br>4 Bureaux de la Colline<br>92213 Saint-Cloud<br>France                         | Ibuprofen            | IBUPROFENE ZYDUS FRANCE<br>200 mg comprimé pelliculé                | 200 mg         | Pillola miksjia b'rita      | Użu orali      |
| Franza              | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France | Ibuprofen            | IBUPROFENE ZYDUS FRANCE<br>400 mg comprimé pelliculé                | 400 mg         | Pillola miksjia b'rita      | Użu orali      |
| Franza              | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France | Tramadol/paracétamol | TRAMADOL PARACETAMOL ZYDUS FRANCE 37,5 mg/325 mg comprimé pelliculé | 37,5 mg/325 mg | Pillola miksjia b'rita      | Użu orali      |
| Franza              | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France | Ibuprofen            | IBUPROFENE ZF 400 mg comprimé pelliculé                             | 400 mg         | Pillola miksjia b'rita      | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                            | INN               | Isem l-vintat                                           | Qawwa | Għamla farmaċewtika     | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------------------------------------|-------------------|---------------------------------------------------------|-------|-------------------------|----------------|
| Franza              | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France                 | Desloratadina     | DESLOTATADINE ZYDUS 5 mg<br>comprimé pelliculé          | 5 mg  | Pillola miksijsa b'rita | Użu orali      |
| Franza              | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France                 | Exxitalopram      | ESCITALOPRAM ZYDUS 5 mg,<br>comprimé pelliculé          | 5 mg  | Pillola miksijsa b'rita | Użu orali      |
| Franza              | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France                 | Exxitalopram      | ESCITALOPRAM ZYDUS 10 mg,<br>comprimé pelliculé sécable | 10 mg | Pillola miksijsa b'rita | Użu orali      |
| Franza              | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France                 | Exxitalopram      | ESCITALOPRAM ZYDUS 15 mg,<br>comprimé pelliculé sécable | 15 mg | Pillola miksijsa b'rita | Użu orali      |
| Franza              | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France                 | Exxitalopram      | ESCITALOPRAM ZYDUS 20 mg,<br>comprimé pelliculé sécable | 20 mg | Pillola miksijsa b'rita | Użu orali      |
| Il-Ġermanja         | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Acidu alendroniku | ALENDRONIC ACID ACCORD<br>70 MG                         | 70 mg | Pillola                 | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                        | INN           | Isem Ivvintat                              | Qawwa    | Għamla farmaċewtika    | Mnein jingħata |
|----------------------|-----------------------------------------------------------------------------|---------------|--------------------------------------------|----------|------------------------|----------------|
| Il-Ġermanja          | Betapharm Arzneimittel GmbH<br>Kobelweg 95<br>D-86156 Augsburg<br>Germany   | Levetiracetam | Levetiracetam beta 250 mg, Filmtabletten   | 250 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Ġermanja          | Betapharm Arzneimittel GmbH<br>Kobelweg 95<br>D-86156 Augsburg<br>Germany   | Levetiracetam | Levetiracetam beta 500 mg, Filmtabletten   | 500 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Ġermanja          | Betapharm Arzneimittel GmbH<br>Kobelweg 95<br>D-86156 Augsburg<br>Germany   | Levetiracetam | Levetiracetam beta 750 mg, Filmtabletten   | 750 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Ġermanja          | Betapharm Arzneimittel GmbH<br>Kobelweg 95<br>D-86156 Augsburg<br>Germany   | Levetiracetam | Levetiracetam beta 1 000 mg, Filmtabletten | 1 000 mg | Pillola miksija b'rita | Użu orali      |
| Il-Ġermanja          | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan    | Irbesartan Tablets 75 mg                   | 75 mg    | Pillola miksija b'rita | Użu orali      |
| Il-Ġermanja          | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan    | Irbesartan Tablets 150 mg                  | 150 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Ġermanja          | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan    | Irbesartan Tablets 300 mg                  | 300 mg   | Pillola miksija b'rita | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                        | INN                         | Isem Ivvintat                                                      | Qawwa          | Għamla farmaċewtika                  | Mnein jingħata |
|----------------------|-----------------------------------------------------------------------------|-----------------------------|--------------------------------------------------------------------|----------------|--------------------------------------|----------------|
| Il-Ġermanja          | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/idroklorotijazid | Irbesartan HCTZ Fair-Med<br>150 + 12,5 mg Filmtabletten            | 150 mg/12,5 mg | Pillola miksija b'rita               | Użu orali      |
| Il-Ġermanja          | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/idroklorotijazid | Irbesartan HCTZ Fair-Med<br>300 + 12,5 mg Filmtabletten            | 300 mg/12,5 mg | Pillola miksija b'rita               | Użu orali      |
| Il-Ġermanja          | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/idroklorotijazid | Irbesartan HCTZ Fair-Med<br>300 + 25 mg Filmtabletten              | 300 mg/25 mg   | Pillola miksija b'rita               | Użu orali      |
| Il-Ġermanja          | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/idroklorotijazid  | Valsartan/HCTZ Fair-Med Healthcare<br>160 mg/12,5 mg Filmtabletten | 160 mg/12,5 mg | Pillola miksija b'rita               | Użu orali      |
| Il-Ġermanja          | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/idroklorotijazid  | Valsartan/HCTZ Fair-Med Healthcare<br>320 mg/12,5 mg Filmtabletten | 320 mg/12,5 mg | Pillola miksija b'rita               | Użu orali      |
| Il-Ġermanja          | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/idroklorotijazid  | Valsartan/HCTZ Fair-Med Healthcare<br>320 mg/25 mg Filmtabletten   | 320 mg/25 mg   | Pillola miksija b'rita               | Użu orali      |
| Il-Ġermanja          | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Venlafaksina                | Venlafaxin Fair-Med 37,5 mg Hartkapseln, retardiert                | 37,5 mg        | Pillola li terhi il-medicina bil-mod | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                 | INN             | Isem l-vintat                                          | Qawwa  | Għamla farmaċewtika                  | Mnejn jingħata |
|---------------------|--------------------------------------------------------------------------------------|-----------------|--------------------------------------------------------|--------|--------------------------------------|----------------|
| Il-Ġermanja         | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany          | Venlafaksina    | Venlafaxin Fair-Med 75 mg Hart-kapseln, retardiert     | 75 mg  | Pillola li terhi il-mediċina bil-mod | Użu orali      |
| Il-Ġermanja         | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany          | Venlafaksina    | Venlafaxin Fair-Med 150 mg Hart-kapseln, retardiert    | 150 mg | Pillola li terhi il-mediċina bil-mod | Użu orali      |
| Il-Ġermanja         | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany          | Ċiprofloksaċina | Ciprofloxacin Fair-Med Healthcare 500 mg Filmtabletten | 500 mg | Pillola miksija b'rita               | Użu orali      |
| Il-Ġermanja         | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany          | Ċiprofloksaċina | Ciprofloxacin Fair-Med Healthcare 750 mg Filmtabletten | 750 mg | Pillola miksija b'rita               | Użu orali      |
| Il-Ġermanja         | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany          | Ċiprofloksaċina | Ciprofloxacin Fair-Med Healthcare 250 mg Filmtabletten | 250 mg | Pillola miksija b'rita               | Użu orali      |
| Il-Ġermanja         | Heumann Pharma GmbH & Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | Irbesartan      | Irbesartan Heumann 75 mg Filmtabletten                 | 75 mg  | Pillola miksija b'rita               | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                         | INN                         | Isem l-vintat                                                      | Qawwa          | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|----------------------------------------------------------------------------------------------|-----------------------------|--------------------------------------------------------------------|----------------|------------------------|----------------|
| Il-Ġermanja         | Heumann Pharma GmbH & Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany         | Irbesartan                  | Irbesartan Heumann 150 mg Filmtabletten                            | 150 mg         | Pillola miksiġa b'rita | Użu orali      |
| Il-Ġermanja         | Heumann Pharma GmbH & Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany         | Irbesartan                  | Irbesartan Heumann 300 mg Filmtabletten                            | 300 mg         | Pillola miksiġa b'rita | Użu orali      |
| Il-Ġermanja         | Heumann Pharma GmbH & Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany         | Irbesartan/idroklorotijazid | Irbesartan/Hydrochlorothiazid Heumann 150 mg/12,5 mg Filmtabletten | 150 mg/12,5 mg | Pillola miksiġa b'rita | Użu orali      |
| Il-Ġermanja         | Heumann Pharma GmbH & Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany         | Irbesartan/idroklorotijazid | Irbesartan/Hydrochlorothiazid Heumann 300 mg/12,5 mg Filmtabletten | 300 mg/12,5 mg | Pillola miksiġa b'rita | Użu orali      |
| Il-Ġermanja         | Heumann Pharma GmbH & Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany         | Irbesartan/idroklorotijazid | Irbesartan/Hydrochlorothiazid Heumann 300 mg/25 mg Filmtabletten   | 300 mg/25 mg   | Pillola miksiġa b'rita | Użu orali      |
| Il-Ġermanja         | Hormosan Pharma GmbH<br>Wilhelmshoeher Str. 106<br>D-60389 Frankfurt<br>06 Hessen<br>Germany | Ċefpodoksima proksetil      | Cefpodoxim-Hormosan 200 mg Filmtabletten                           | 200 mg         | Pillola miksiġa b'rita | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                    | INN                      | Isem Ivvintat                               | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------------------------------|--------------------------|---------------------------------------------|--------|-----------------------------|----------------|
| Il-Ġermanja          | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16 0PF<br>United Kingdom | Trimetazidina kloridrata | Lupomadazine 35 mg Retardtabletten          | 35 mg  | Pillola li terhi kontrollat | Użu orali      |
| Il-Ġermanja          | Micro Labs GmbH<br>Lyoner Str. 14<br>D-60528 Frankfurt/Main<br>Germany                                  | Exxitalopram             | Escitalopram-Micro Labs 5 mg Filmtabletten  | 5 mg   | Pillola miksija b'rita      | Użu orali      |
| Il-Ġermanja          | Micro Labs GmbH<br>Lyoner Str. 14<br>D-60528 Frankfurt/Main<br>Germany                                  | Exxitalopram             | Escitalopram-Micro Labs 10 mg Filmtabletten | 10 mg  | Pillola miksija b'rita      | Użu orali      |
| Il-Ġermanja          | Micro Labs GmbH<br>Lyoner Str. 14<br>D-60528 Frankfurt/Main<br>Germany                                  | Exxitalopram             | Escitalopram-Micro Labs 15 mg Filmtabletten | 15 mg  | Pillola miksija b'rita      | Użu orali      |
| Il-Ġermanja          | Micro Labs GmbH<br>Lyoner Str. 14<br>D-60528 Frankfurt/Main<br>Germany                                  | Exxitalopram             | Escitalopram-Micro Labs 20 mg Filmtabletten | 20 mg  | Pillola miksija b'rita      | Użu orali      |
| Il-Ġermanja          | Mylan dura GmbH<br>Wittichstrasse 6<br>64295 Darmstadt<br>Germany                                       | Repaglinid               | Repaglinid Mylan 0,5 mg Tabletten           | 0,5 mg | Pillola                     | Użu orali      |
| Il-Ġermanja          | Mylan dura GmbH<br>Wittichstrasse 6<br>64295 Darmstadt<br>Germany                                       | Repaglinid               | Repaglinid Mylan 1 mg Tabletten             | 1 mg   | Pillola                     | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                               | INN         | Isem Ivvintat                                 | Qawwa  | Għamla farmaċewtika         | Mnein jingħata |
|----------------------|------------------------------------------------------------------------------------|-------------|-----------------------------------------------|--------|-----------------------------|----------------|
| Il-Ġermanja          | Mylan dura GmbH<br>Wittichstrasse 6<br>64295 Darmstadt<br>Germany                  | Repaglinid  | Repaglinid Mylan 2 mg Tabletten               | 2 mg   | Pillola                     | Użu orali      |
| Il-Ġermanja          | Mylan dura GmbH<br>Wittichstrasse 6<br>64295 Darmstadt<br>Germany                  | Rizatriptan | Rizatriptan Mylan dura 5 mg Schmelztabletten  | 5 mg   | Pillola li tinhall fil-halq | Użu orali      |
| Il-Ġermanja          | Mylan dura GmbH<br>Wittichstrasse 6<br>64295 Darmstadt<br>Germany                  | Rizatriptan | Rizatriptan Mylan dura 10 mg Schmelztabletten | 10 mg  | Pillola li tinhall fil-halq | Użu orali      |
| Il-Ġermanja          | Panacea Biotec Germany GmbH<br>Landshuter Allee 8-10<br>D-80637 München<br>Germany | Takrolimus  | Tacpan 0,5 mg Hartkapseln                     | 0,5 mg | Kapsula, iebsa              | Użu orali      |
| Il-Ġermanja          | Panacea Biotec Germany GmbH<br>Landshuter Allee 8-10<br>D-80637 München<br>Germany | Takrolimus  | Tacpan 1 mg Hartkapseln                       | 1 mg   | Kapsula, iebsa              | Użu orali      |
| Il-Ġermanja          | Panacea Biotec Germany GmbH<br>Landshuter Allee 8-10<br>D-80637 München<br>Germany | Takrolimus  | Tacpan 5 mg Hartkapseln                       | 5 mg   | Kapsula, iebsa              | Użu orali      |
| Il-Ġermanja          | Stadapharm GmbH<br>Stadastr. 2-18<br>D-61118 Bad Vilbel<br>Germany                 | Entakapon   | Entacapon STADA 200 mg Filmtabletten          | 200 mg | Pillola miksija b'rita      | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                                                      | INN                         | Isem l-vintat                            | Qawwa          | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------------------------------|----------------|------------------------|----------------|
| Il-Ġermanja         | Unichem Laboratories Ltd.<br>Studio 8B Ard Gaoithe Commercial<br>Centre, Business Park<br>Cashel Road Clonmel,<br>Co Tipperary<br>Ireland | Irbesartan                  | Irbesartan Unichem 150 mg Film-tabletten | 150 mg         | Pillola miksija b'rita | Użu orali      |
| Il-Ġermanja         | Unichem Laboratories Ltd.<br>Studio 8B Ard Gaoithe Commercial<br>Centre, Business Park<br>Cashel Road Clonmel,<br>Co Tipperary<br>Ireland | Irbesartan                  | Irbesartan Unichem 300 mg Film-tabletten | 300 mg         | Pillola miksija b'rita | Użu orali      |
| Il-Ġermanja         | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                                                       | Irbesartan/idroklorotijazid | Irbesartan + Hidroklorotiazida Welding   | 300 mg/12,5 mg | Pillola miksija b'rita | Użu orali      |
| Il-Ġermanja         | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                                                       | Irbesartan/idroklorotijazid | Irbesartan + Hidroklorotiazida Welding   | 150 mg/12,5 mg | Pillola miksija b'rita | Użu orali      |
| Il-Ġermanja         | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                                                       | Irbesartan/idroklorotijazid | Irbesartan + Hidroklorotiazida Welding   | 300 mg/25 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Ġermanja         | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                                                       | Irbesartan                  | Irbesartan Welding                       | 75 mg          | Pillola miksija b'rita | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                               | INN                           | Isem Ivvintat      | Qawwa  | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|------------------------------------------------------------------------------------|-------------------------------|--------------------|--------|------------------------|----------------|
| Il-Ġermanja         | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                | Irbesartan                    | Irbesartan Welding | 150 mg | Pillola miksija b'rita | Użu orali      |
| Il-Ġermanja         | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                | Irbesartan                    | Irbesartan Welding | 300 mg | Pillola miksija b'rita | Użu orali      |
| Il-Greċja           | Abbott Laboratories<br>Hellas ABEE<br>Agiou Dimitriou 63<br>Alimos 17456<br>Greece | Ossalat tal-exxitalo-<br>pram | Savandra           | 5 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Greċja           | Abbott Laboratories<br>Hellas ABEE<br>Agiou Dimitriou 63<br>Alimos 17456<br>Greece | Ossalat tal-exxitalo-<br>pram | Savandra           | 10 mg  | Pillola miksija b'rita | Użu orali      |
| Il-Greċja           | Abbott Laboratories<br>Hellas ABEE<br>Agiou Dimitriou 63<br>Alimos 17456<br>Greece | Ossalat tal-exxitalo-<br>pram | Savandra           | 15 mg  | Pillola miksija b'rita | Użu orali      |
| Il-Greċja           | Abbott Laboratories<br>Hellas ABEE<br>Agiou Dimitriou 63<br>Alimos 17456<br>Greece | Ossalat tal-exxitalo-<br>pram | Savandra           | 20 mg  | Pillola miksija b'rita | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                             | INN                  | Isem l-vintat                                                   | Qawwa  | Għamla farmaċewtika                 | Mnejn jingħata |
|----------------------|--------------------------------------------------------------------------------------------------|----------------------|-----------------------------------------------------------------|--------|-------------------------------------|----------------|
| Il-Greċja            | Geneparm S.A.<br>18 Km Marathon Avenue, 15351 Pallini<br>Greece                                  | Desloratadina        | Desloratadine/Geneparm 5 mg<br>δισκία επικαλυμμένα με υμένιο,   | 5 mg   | Pillola miksija b'rita              | Użu orali      |
| Il-Greċja            | Geneparm S.A.<br>18 Km Marathon Avenue, 15351 Pallini<br>Greece                                  | Desloratadina        | Desloratadine/Geneparm 2,5 mg<br>δισκία διασπειρόμενα στο στόμα | 2,5 mg | Pillola li tinħall fil-halq         | Użu orali      |
| Il-Greċja            | Geneparm S.A.<br>18 Km Marathon Avenue, 15351 Pallini<br>Greece                                  | Desloratadina        | Desloratadine/Geneparm 5 mg<br>δισκία διασπειρόμενα στο στόμα   | 5 mg   | Pillola li tinħall fil-halq         | Użu orali      |
| Il-Greċja            | Generics Pharma Hellas Ltd<br>577a Vouliagmenis Avenue<br>Argyroupoli<br>164-51 Athens<br>Greece | Donepezil kloridrat  | Donepezil/Generics                                              | 5 mg   | Pillola li tinħall fil-halq         | Użu orali      |
| Il-Greċja            | Generics Pharma Hellas Ltd<br>577a Vouliagmenis Avenue<br>Argyroupoli<br>164-51 Athens<br>Greece | Donepezil kloridrat  | Donepezil/Generics                                              | 10 mg  | Pillola li tinħall fil-halq         | Użu orali      |
| Il-Greċja            | Generics Pharma Hellas Ltd<br>577a Vouliagmenis Avenue<br>Argyroupoli<br>164-51 Athens<br>Greece | Ezomeprazol manjeżju | Esomeprazole/Generics                                           | 40 mg  | Kapsula li terhi l-medicina bil-mod | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                            | INN                   | Isem Ivvintat                                   | Qawwa  | Għamla farmaċewtika                       | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------|-----------------------|-------------------------------------------------|--------|-------------------------------------------|----------------|
| Il-Greċja            | Sieger Pharma A.E.<br>Marathonos Avenue 106<br>Pikermi 19009<br>Greece          | Desloratadina         | Desloratadine/Sieger                            | 5 mg   | Pillola miksija b'rita                    | Użu orali      |
| Il-Greċja            | Sieger Pharma A.E.<br>Marathonos Avenue 106<br>Pikermi 19009<br>Greece          | Desloratadina         | Desloratadine/Sieger                            | 2,5 mg | Pillola li tinħall fil-halq               | Użu orali      |
| Il-Greċja            | Sieger Pharma A.E.<br>Marathonos Avenue 106<br>Pikermi 19009<br>Greece          | Desloratadina         | Desloratadine/Sieger                            | 5 mg   | Pillola li tinħall fil-halq               | Użu orali      |
| L-Ungerija           | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland | Metformina kloridrata | Gluforlyn XR 500 mg retard tabletta             | 500 mg | Pillola li terhi il-medi-<br>ċina bil-mod | Użu orali      |
| L-Ungerija           | Alvogen IPCo S.ar.l.<br>Rue Heienhaff 5<br>L-1736 Senningerberg<br>Lussemburgu  | Desloratadina         | Alvotadin 5 mg filmtabletta                     | 5 mg   | Pillola miksija b'rita                    | Użu orali      |
| L-Ungerija           | Alvogen IPCo S.ar.l.<br>Rue Heienhaff 5<br>L-1736 Senningerberg<br>Lussemburgu  | Desloratadina         | Alvotadin 2,5 mg szájban diszpergálódó tabletta | 2,5 mg | Pillola li tinħall fil-halq               | Użu orali      |
| L-Ungerija           | Alvogen IPCo S.ar.l.<br>Rue Heienhaff 5<br>L-1736 Senningerberg<br>Lussemburgu  | Desloratadina         | Alvotadin 5 mg szájban diszpergálódó tabletta   | 5 mg   | Pillola li tinħall fil-halq               | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                        | INN                        | Isem Ivvintat                                                 | Qawwa  | Għamla farmaċewtika                   | Mnein jingħata |
|----------------------|---------------------------------------------------------------------------------------------|----------------------------|---------------------------------------------------------------|--------|---------------------------------------|----------------|
| L-Ungerija           | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Ezomeprazol manjeżju       | Esomeprazol Mylan 20 mg gvo-mornedv-ellenálló kemény kapszula | 20 mg  | Kapsula gastro-reżis-tenti, iebša     | Użu orali      |
| L-Ungerija           | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Ezomeprazol manjeżju       | Esomeprazol Mylan 40 mg gvo-mornedv-ellenálló kemény kapszula | 40 mg  | Kapsula gastro-reżis-tenti, iebša     | Użu orali      |
| L-Ungerija           | Glenmark Pharmaceuticals s.r.o.<br>Hvězdova 1716/2b<br>14078 Praha 4<br>Czech Republic      | Trimetažidina dikloridrata | Apstar 35 mg retard tabletta                                  | 35 mg  | Pillola li terhi il-medi-čina bil-mod | Użu orali      |
| L-Ungerija           | Goodwill Pharma Kft.<br>H-6724 Szeged<br>Cserzy Mihály u. 32.<br>Hungary                    | Desloratadina              | Inaller 5 mg filmtabletta                                     | 5 mg   | Pillola miksijsja b'rita              | Użu orali      |
| L-Ungerija           | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                      | Trimetažidina              | Trimetazidine Mylan 35 mg retard tabletta                     | 35 mg  | Pillola li terhi il-medi-čina bil-mod | Użu orali      |
| L-Ungerija           | Sandoz Hungária Kft.<br>H-1114 Budapest<br>Bartók Béla út 43-47.<br>Hungary                 | Trimetažidina dikloridrata | Trimetazidine Sandoz 35 mg retard tabletta                    | 35 mg  | Pillola li terhi il-medi-čina bil-mod | Użu orali      |
| L-Ungerija           | Teva Gyógyszergyár Zrt.<br>H-4042 Debrecen<br>Pallagi út 13.<br>Hungary                     | Desloratadina              | Desloratadin Teva 2,5 mg száiban diszpergalódó tabletta       | 2,5 mg | Pillola li tinħall fil-ħalq           | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                            | INN                 | Isem l-vintat                                            | Qawwa   | Għamla farmaċewtika         | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------------------------------------|---------------------|----------------------------------------------------------|---------|-----------------------------|----------------|
| L-Ungerija           | Teva Gyógyszergyár Zrt.<br>H-4042 Debrecen<br>Pallagi út 13.<br>Hungary                                         | Desloratadina       | Desloratadin Teva 5 mg szájban<br>diszpergálódó tabletta | 5 mg    | Pillola li tinħall fil-halq | Użu orali      |
| Islanda              | Ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>D-89079 Ulm<br>Germany                                                | Desloratadina       | Desloratadine ratiopharm                                 | 5 mg    | Pillola li tinħall fil-halq | Użu orali      |
| L-Irlanda            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol kloridrat | Ropinirole 0,25 mg Film-coated<br>Tablets                | 0,25 mg | Pillola miksija b'rita      | Użu orali      |
| L-Irlanda            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol kloridrat | Ropinirole 0,5 mg Film-coated Ta-<br>blets               | 0,5 mg  | Pillola miksija b'rita      | Użu orali      |
| L-Irlanda            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol kloridrat | Ropinirole 1 mg Film-coated Tablets                      | 1 mg    | Pillola miksija b'rita      | Użu orali      |
| L-Irlanda            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol kloridrat | Ropinirole 2 mg Film-coated Tablets                      | 2 mg    | Pillola miksija b'rita      | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                                    | INN                        | Isem l-vintat                                                              | Qawwa          | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|-------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------------------------------------------------------------|----------------|------------------------|----------------|
| L-Irlanda           | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom         | Ropinirol kloridrat        | Ropinirole 5 mg Film-coated Tablets                                        | 5 mg           | Pillola miksija b'rita | Użu orali      |
| L-Irlanda           | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom         | Acidu alendroniku          | Alendronic Acid Once Weekly<br>70 mg Tablets                               | 70 mg          | Pillola                | Użu orali      |
| L-Irlanda           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                             | Valsartan/idroklorotijazid | Valsartan/Hydrochlorothiazide Fair-Med 160 mg/12,5 mg film-coated tablets. | 160 mg/12,5 mg | Pillola miksija b'rita | Użu orali      |
| L-Irlanda           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                             | Valsartan/idroklorotijazid | Valsartan/Hydrochlorothiazide Fair-Med 320 mg/12,5 mg film-coated tablets  | 320 mg/12,5 mg | Pillola miksija b'rita | Użu orali      |
| L-Irlanda           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                             | Valsartan/idroklorotijazid | Valsartan/Hydrochlorothiazide Fair-Med 320 mg/25 mg film-coated tablets    | 320 mg/25 mg   | Pillola miksija b'rita | Użu orali      |
| L-Irlanda           | Fannin (UK) Ltd<br>42-46 Booth Drive<br>Park Farm South<br>Wellingborough<br>Northamptonshire NN8 6GT<br>United Kingdom | Feksofenadina kloridrata   | Fexofenadine 120 mg film-coated tablets                                    | 120 mg         | Pillola miksija b'rita | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                                            | INN                      | Isem l-vintat                                            | Qawwa  | Għamla farmaċewtika              | Mnejn jingħata |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------------------------------------------|--------|----------------------------------|----------------|
| L-Irlanda           | Fannin (UK) Ltd<br>42-46 Booth Drive<br>Park Farm South<br>Wellingborough<br>Northamptonshire NN8 6GT<br>United Kingdom         | Feksofenadina kloridrata | Fexofenadine 180 mg film-coated tablets                  | 180 mg | Pillola miksija b'rita           | Użu orali      |
| L-Irlanda           | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoye Industrial Estate<br>Grange Road<br>Dublin 13<br>Ireland | Donepezil                | Aripil Orotab 5 mg Orodispersible Tablet                 | 5 mg   | Pillola li tinħall fil-halq      | Użu orali      |
| L-Irlanda           | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoye Industrial Estate<br>Grange Road<br>Dublin 13<br>Ireland | Donepezil                | Aripil Orotab 10 mg Orodispersible Tablet                | 10 mg  | Pillola li tinħall fil-halq      | Użu orali      |
| L-Irlanda           | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoye Industrial Estate<br>Grange Road<br>Dublin 13<br>Ireland | Ezomeprazol              | Esomeprazole Mylan 20 mg Gastro-resistant Capsules, hard | 20 mg  | Kapsula gastro-reżistenti, iebsa | Użu orali      |
| L-Irlanda           | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoye Industrial Estate<br>Grange Road<br>Dublin 13<br>Ireland | Ezomeprazol              | Esomeprazole Mylan 40 mg Gastro-resistant Capsules, hard | 40 mg  | Kapsula gastro-reżistenti, iebsa | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                                            | INN                      | Isem l-vintat                                         | Qawwa  | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------|--------------------------|-------------------------------------------------------|--------|------------------------|----------------|
| L-Irlanda           | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoye Industrial Estate<br>Grange Road<br>Dublin 13<br>Ireland | Kandesartan              | Candesartan Mylan 4 mg Tablets                        | 4 mg   | Pillola                | Użu orali      |
| L-Irlanda           | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoye Industrial Estate<br>Grange Road<br>Dublin 13<br>Ireland | Kandesartan              | Candesartan Mylan 8 mg Tablets                        | 8 mg   | Pillola                | Użu orali      |
| L-Irlanda           | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoye Industrial Estate<br>Grange Road<br>Dublin 13<br>Ireland | Kandesartan              | Candesartan Mylan 16 mg Tablets                       | 16 mg  | Pillola                | Użu orali      |
| L-Irlanda           | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoye Industrial Estate<br>Grange Road<br>Dublin 13<br>Ireland | Kandesartan              | Candesartan Mylan 32 mg Tablets                       | 32 mg  | Pillola                | Użu orali      |
| L-Irlanda           | Morningside Healthcare Limited<br>115 Narborough Road<br>Leicester, LE3 0PA<br>United Kingdom                                   | Fenoksimetil penicillina | Phenoxymethylpenicillin 250 mg<br>Film-coated Tablets | 250 mg | Pillola miksija b'rita | Użu orali      |
| L-Irlanda           | Niche Generics Limited<br>1 The Cam Centre<br>Wilbury Way, Hitchin<br>Hertfordshire SG4 0TW<br>United Kingdom                   | Besilat tal-amlodipina   | Amlodipine Niche 5 mg tablets                         | 5 mg   | Pillola                | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                            | INN                    | Isem l-vintat                               | Qawwa  | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------------------------------------|------------------------|---------------------------------------------|--------|------------------------|----------------|
| L-Irlanda           | Niche Generics Limited<br>1 The Cam Centre<br>Wilbury Way, Hitchin<br>Hertfordshire SG4 0TW<br>United Kingdom   | Besilat tal-amlodipina | Amlodipine Niche 10 mg Tablets              | 10 mg  | Pillola                | Użu orali      |
| L-Irlanda           | Niche Generics Limited<br>1 The Cam Centre<br>Wilbury Way, Hitchin<br>Hertfordshire SG4 0TW<br>United Kingdom   | Irbesartan             | Irbesartan Niche 150 mg film coated tablets | 150 mg | Pillola miksija b'rita | Użu orali      |
| L-Irlanda           | Niche Generics Limited<br>1 The Cam Centre<br>Wilbury Way, Hitchin<br>Hertfordshire SG4 0TW<br>United Kingdom   | Irbesartan             | Irbesartan Niche 300 mg film coated tablets | 300 mg | Pillola miksija b'rita | Użu orali      |
| L-Irlanda           | Wockhardt UK Limited<br>Ash Road North<br>Wrexham Industrial Estate<br>Wrexham LL13 9UF<br>United Kingdom       | Klopidoġrel kloridrat  | Clopidogrel 75 mg film-coated tablets       | 75 mg  | Pillola miksija b'rita | Użu orali      |
| L-Italja            | Accord Healthcare Italia S.r.l.<br>Largo Esterle, 4<br>20052 Monza<br>Italy                                     | Metoklopramid          | METOCLOPRAMIDE ACCORD                       | 10 mg  | Pillola                | Użu orali      |
| L-Italja            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Acidu alendroniku      | ALENDRONATO AHCL                            | 10 mg  | Pillola                | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                            | INN               | Isem Ivvintat              | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------------------------------------|-------------------|----------------------------|--------|-----------------------------|----------------|
| L-Italja            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Acidu alendroniku | ALENDRONATO AHCL           | 70 mg  | Pillola                     | Użu orali      |
| L-Italja            | Doc Generici SRL<br>Via Turati, 40<br>20121 Milano<br>Italy                                                     | Desloratadina     | DESLOTATADINA DOC GENERICI | 5 mg   | Pillola miksija b'rita      | Użu orali      |
| L-Italja            | Doc Generici SRL<br>Via Turati, 40<br>20121 Milano<br>Italy                                                     | Desloratadina     | DESLOTATADINA DOC GENERICI | 2,5 mg | Pillola li tinħall fil-halq | Użu orali      |
| L-Italja            | Doc Generici SRL<br>Via Turati, 40<br>20121 Milano<br>Italy                                                     | Desloratadina     | DESLOTATADINA DOC GENERICI | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| L-Italja            | Farmaceutici Caber S.P.A.<br>Viale Citta' D'Europa, 681<br>00144 Rome<br>Italy                                  | Valsartan         | VALSOTEN                   | 40 mg  | Pillola miksija b'rita      | Użu orali      |
| L-Italja            | Farmaceutici Caber S.P.A.<br>Viale Citta' D'Europa, 681<br>00144 Rome<br>Italy                                  | Valsartan         | VALSOTEN                   | 80 mg  | Pillola miksija b'rita      | Użu orali      |
| L-Italja            | Farmaceutici Caber S.P.A.<br>Viale Citta' D'Europa, 681<br>00144 Rome<br>Italy                                  | Valsartan         | VALSOTEN                   | 160 mg | Pillola miksija b'rita      | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                           | INN                     | Isem Ivvintat                      | Qawwa  | Għamla farmaċewtika                   | Mnejn jingħata |
|---------------------|--------------------------------------------------------------------------------|-------------------------|------------------------------------|--------|---------------------------------------|----------------|
| L-Italja            | Farmaceutici Caber S.P.A.<br>Viale Citta' D'Europa, 681<br>00144 Rome<br>Italy | Valsartan               | VALSOTEN                           | 320 mg | Pillola miksija b'rita                | Użu orali      |
| L-Italja            | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                  | Eżomeprażol manjeżju    | ESOMEPRAZOLO MYLAN                 | 20 mg  | Kapsula gastro-reżis-<br>tenti, iebša | Użu orali      |
| L-Italja            | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                  | Eżomeprażol manjeżju    | ESOMEPRAZOLO MYLAN                 | 40 mg  | Kapsula gastro-reżis-<br>tenti, iebša | Użu orali      |
| L-Italja            | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                  | Benżoat tar-rizatriptan | RIAZATRIPTAN MYLAN GENE-<br>RICS   | 5 mg   | Pillola li tinħall fil-halq           | Użu orali      |
| L-Italja            | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                  | Benżoat tar-rizatriptan | RIAZATRIPTAN MYLAN GENE-<br>RICS   | 10 mg  | Pillola li tinħall fil-halq           | Użu orali      |
| L-Italja            | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                  | Donepezil kloridrat     | DONEPEZIL MYLAN GENERICS<br>ITALIA | 5 mg   | Pillola li tinħall fil-halq           | Użu orali      |
| L-Italja            | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                  | Donepezil kloridrat     | DONEPEZIL MYLAN GENERICS<br>ITALIA | 10 mg  | Pillola li tinħall fil-halq           | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                            | INN                        | Isem Ivvintat                        | Qawwa  | Għamla farmaċewtika                          | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------------------------------------|----------------------------|--------------------------------------|--------|----------------------------------------------|----------------|
| L-Italja             | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                                                   | Repaglinid                 | REPAGLINIDE MYLAN                    | 0,5 mg | Pillola                                      | Użu orali      |
| L-Italja             | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                                                   | Repaglinid                 | REPAGLINIDE MYLAN                    | 1 mg   | Pillola                                      | Użu orali      |
| L-Italja             | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                                                   | Repaglinid                 | REPAGLINIDE MYLAN                    | 2 mg   | Pillola                                      | Użu orali      |
| L-Italja             | Pensa Pharma S.P.A.<br>Via Rossellini Ippolito, 12<br>20124 Milan<br>Italy                                      | Acidu alendroniku          | Alendronato Pensa<br>70 mg compresse | 70 mg  | Pillola                                      | Użu orali      |
| L-Italja             | Ranbaxy Italia S.P.A.<br>Piazza Filippo Meda, 4, 3<br>20121 – Milano<br>Italy                                   | Acidu alendroniku          | ALENDRONATO RANBAXY ITA-LIA          | 70 mg  | Pillola                                      | Użu orali      |
| Il-Latvja            | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia                                   | Trimetažidina dikloridrata | Zidmetin                             | 35 mg  | Pillola li terhi il-medicina b'mod modifikat | Użu orali      |
| Il-Litwanja          | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Acidu alendroniku          | Alendronic acid Accord               | 70 mg  | Pillola                                      | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                             | INN        | Isem Ivvintat        | Qawwa  | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|------------------------------------------------------------------------------------------------------------------|------------|----------------------|--------|------------------------|----------------|
| Il-Litwanja         | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirol  | Ropinirole Lambada   | 0,5 mg | Pillola miksija b'rita | Użu orali      |
| Il-Litwanja         | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirol  | Ropinirole Lambada   | 1 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Litwanja         | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirol  | Ropinirole Lambada   | 2 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Litwanja         | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirol  | Ropinirole Lambada   | 5 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Litwanja         | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                                               | Irbesartan | Irbesartanas Torrent | 75 mg  | Pillola miksija b'rita | Użu orali      |
| Il-Litwanja         | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                                               | Irbesartan | Irbesartanas Torrent | 150 mg | Pillola miksija b'rita | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                 | INN                         | Isem Ivvintat                                | Qawwa          | Għamla farmaċewtika    | Mnejn jingħata |
|----------------------|----------------------------------------------------------------------|-----------------------------|----------------------------------------------|----------------|------------------------|----------------|
| Il-Litwanja          | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany   | Irbesartan                  | Irbesartanas Torrent                         | 300 mg         | Pillola miksija b'rita | Użu orali      |
| Il-Litwanja          | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany   | Irbesartan/idroklorotijazid | Irbesartanas/Hidrochlorotiazidas<br>Torrent  | 150 mg/12,5 mg | Pillola miksija b'rita | Użu orali      |
| Il-Litwanja          | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany   | Irbesartan/idroklorotijazid | Irbesartanas/Hidrochlorotiazidas<br>Torrent  | 300 mg/12,5 mg | Pillola miksija b'rita | Użu orali      |
| Il-Litwanja          | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany   | Irbesartan/idroklorotijazid | Irbesartanas/Hidrochlorotiazidas<br>Torrent  | 300 mg/25 mg   | Pillola miksija b'rita | Użu orali      |
| Il-Lussemburgu       | Mylan bvba/sprl<br>Terhulpesteenweg 6 A<br>1560 Hoeilaart<br>Belgium | Repaglinid                  | Repaglinide Mylan Pharma 0,5 mg<br>tabletten | 0,5 mg         | Pillola                | Użu orali      |
| Il-Lussemburgu       | Mylan bvba/sprl<br>Terhulpesteenweg 6 A<br>1560 Hoeilaart<br>Belgium | Repaglinid                  | Repaglinide Mylan Pharma 1 mg<br>tabletten   | 1 mg           | Pillola                | Użu orali      |
| Il-Lussemburgu       | Mylan bvba/sprl<br>Terhulpesteenweg 6 A<br>1560 Hoeilaart<br>Belgium | Repaglinid                  | Repaglinide Mylan Pharma 2 mg<br>tabletten   | 2 mg           | Pillola                | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                        | INN                       | Isem Ivvintat                                          | Qawwa          | Għamla farmaċewtika              | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------|---------------------------|--------------------------------------------------------|----------------|----------------------------------|----------------|
| Il-Lussemburgu      | Mylan bvba/sprl<br>Terhulpssteenweg 6 A<br>1560 Hoeilaart<br>Belgium        | Ezomeprazol               | Esomeprazole Mylan                                     | 20 mg          | Kapsula gastro-reżistenti, iebsa | Użu orali      |
| Il-Lussemburgu      | Mylan bvba/sprl<br>Terhulpssteenweg 6 A<br>1560 Hoeilaart<br>Belgium        | Ezomeprazol               | Esomeprazole Mylan                                     | 40 mg          | Kapsula gastro-reżistenti, iebsa | Użu orali      |
| Malta               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/idroklorotiazid | Valsartan/hydrochlorothiazid "Fair-Med" Coated tablets | 160 mg/12,5 mg | Pillola miksija b'rita           | Użu orali      |
| Malta               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/idroklorotiazid | Valsartan/hydrochlorothiazid "Fair-Med" Coated tablets | 320 mg/12,5 mg | Pillola miksija b'rita           | Użu orali      |
| Malta               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/idroklorotiazid | Valsartan/hydrochlorothiazid "Fair-Med" Coated tablets | 320 mg/25 mg   | Pillola miksija b'rita           | Użu orali      |
| Malta               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Ċiprofloksacina           | Ciprofloxacin Fair-Med Coated Tablets                  | 250 mg         | Pillola miksija b'rita           | Użu orali      |
| Malta               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Ċiprofloksacina           | Ciprofloxacin Fair-Med Coated Tablets                  | 500 mg         | Pillola miksija b'rita           | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                        | INN                         | Isem Ivvintat                                                             | Qawwa          | Għamla farmaċewtika                              | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------|-----------------------------|---------------------------------------------------------------------------|----------------|--------------------------------------------------|----------------|
| Malta                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | irbesartan                  | Irbesartan Fairmed 75 mg Film-coated Tablets                              | 75 mg          | Pillola miksija b'rita                           | Użu orali      |
| Malta                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | irbesartan                  | Irbesartan Fairmed 150 mg Film-coated Tablets                             | 150 mg         | Pillola miksija b'rita                           | Użu orali      |
| Malta                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | irbesartan                  | Irbesartan Fairmed 300 mg Film-coated Tablets                             | 300 mg         | Pillola miksija b'rita                           | Użu orali      |
| Malta                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/idroklorotijazid | Irbesartan/Hydrochlorothiazide Fairmed 150 mg/12,5 mg film-coated tablets | 150 mg/12,5 mg | Pillola miksija b'rita                           | Użu orali      |
| Malta                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/idroklorotijazid | Irbesartan/Hydrochlorothiazide Fairmed 300 mg/12,5 mg film-coated tablets | 300 mg/12,5 mg | Pillola miksija b'rita                           | Użu orali      |
| Malta                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/idroklorotijazid | Irbesartan/Hydrochlorothiazide Fairmed 300 mg/25 mg film-coated tablets   | 300 mg/25 mg   | Pillola miksija b'rita                           | Użu orali      |
| Malta                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Venlafaksina                | Venlafaxine Fair-Med                                                      | 37,5 mg        | Kapsula li terfi l-medikazzjoni bil-mod, iebesja | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                      | INN          | Isem Ivvintat                         | Qawwa  | Għamla farmaċewtika                         | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------------------------------|--------------|---------------------------------------|--------|---------------------------------------------|----------------|
| Malta                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                               | Venlafaksina | Venlafaxine Fair-Med                  | 75 mg  | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Malta                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                               | Venlafaksina | Venlafaxine Fair-Med                  | 150 mg | Kapsula li terfhi l-medicina bil-mod, iebsa | Użu orali      |
| Malta                | Wockhardt UK Limited<br>Ash Road North<br>Wrexham Industrial Estate<br>Wrexham LL13 9UF<br>United Kingdom | Klopidoġrel  | Clopidogrel 75 mg Film-coated Tablets | 75 mg  | Pillola miksija b'rita                      | Użu orali      |
| Malta                | Wockhardt UK Limited<br>Ash Road North<br>Wrexham Industrial Estate<br>Wrexham LL13 9UF<br>United Kingdom | Klopidoġrel  | Clopidogrel 75 mg Coated Tablets      | 75 mg  | Pillola miksija b'rita                      | Użu orali      |
| In-Norveġja          | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                               | Flukonazol   | Fluconazol Bluefish                   | 50 mg  | Kapsula, iebsa                              | Użu orali      |
| In-Norveġja          | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                               | Flukonazol   | Fluconazol Bluefish                   | 150 mg | Kapsula, iebsa                              | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                        | INN                    | Isem Ivvintat       | Qawwa  | Għamla farmaċewtika              | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------|------------------------|---------------------|--------|----------------------------------|----------------|
| In-Norveġja          | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Flukonazol             | Fluconazol Bluefish | 200 mg | Kapsula, iebsa                   | Użu orali      |
| In-Norveġja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Ežomeprazol            | Esomeprazol Mylan   | 20 mg  | Kapsula gastro-reżistenti, iebsa | Użu orali      |
| In-Norveġja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Ežomeprazol            | Esomeprazol Mylan   | 40 mg  | Kapsula gastro-reżistenti, iebsa | Użu orali      |
| In-Norveġja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Eletriptan             | Eletriptan Mylan    | 20 mg  | Pillola miksija b'rita           | Użu orali      |
| In-Norveġja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Eletriptan             | Eletriptan Mylan    | 40 mg  | Pillola miksija b'rita           | Użu orali      |
| In-Norveġja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Kandesartan ċileksetil | Kandrozid           | 4 mg   | Pillola                          | Użu orali      |
| In-Norveġja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Kandesartan ċileksetil | Kandrozid           | 8 mg   | Pillola                          | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq             | INN                    | Isem Ivvintat                                     | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|----------------------|------------------------------------------------------------------|------------------------|---------------------------------------------------|--------|-----------------------------|----------------|
| In-Norveġja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden       | Kandesartan ċileksetil | Kandrozid                                         | 16 mg  | Pillola                     | Użu orali      |
| In-Norveġja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden       | Kandesartan ċileksetil | Kandrozid                                         | 32 mg  | Pillola                     | Użu orali      |
| In-Norveġja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden       | Kandesartan ċileksetil | Mylcande                                          | 8 mg   | Pillola                     | Użu orali      |
| In-Norveġja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden       | Kandesartan ċileksetil | Mylcande                                          | 16 mg  | Pillola                     | Użu orali      |
| In-Norveġja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden       | Kandesartan ċileksetil | Mylcande                                          | 32 mg  | Pillola                     | Użu orali      |
| In-Norveġja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden       | Rizatriptan            | RIZATRIPTAN MYLAN 10 mg,<br>orodispersible tablet | 10 mg  | Pillola li tinħall fil-halq | Użu orali      |
| In-Norveġja          | Ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>D-89079 Ulm<br>Germany | Desloratadina          | Desloratadin Ratiopharm                           | 2,5 mg | Pillola li tinħall fil-halq | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                  | INN           | Isem Ivvintat           | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------------|---------------|-------------------------|--------|-----------------------------|----------------|
| In-Norveġja          | Ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>D-89079 Ulm<br>Germany                      | Desloratadina | Desloratadin Ratiopharm | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| Il-Polonja           | Abbott Laboratories Poland Sp. z o.o.<br>ul. Postępu 21B<br>02-676 Warszawa<br>Poland | Exxitalopram  | Savandra                | 5 mg   | Pillola miksija b'rita      | Użu orali      |
| Il-Polonja           | Abbott Laboratories Poland Sp. z o.o.<br>ul. Postępu 21B<br>02-676 Warszawa<br>Poland | Exxitalopram  | Savandra                | 10 mg  | Pillola miksija b'rita      | Użu orali      |
| Il-Polonja           | Abbott Laboratories Poland Sp. z o.o.<br>ul. Postępu 21B<br>02-676 Warszawa<br>Poland | Exxitalopram  | Savandra                | 15 mg  | Pillola miksija b'rita      | Użu orali      |
| Il-Polonja           | Abbott Laboratories Poland Sp. z o.o.<br>ul. Postępu 21B<br>02-676 Warszawa<br>Poland | Exxitalopram  | Savandra                | 20 mg  | Pillola miksija b'rita      | Użu orali      |
| Il-Polonja           | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland       | Metformina    | Metformin SR Actavis    | 500 mg | Pillola miksija b'rita      | Użu orali      |
| Il-Polonja           | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland       | Metformina    | Metformin SR Actavis    | 750 mg | Pillola miksija b'rita      | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                         | INN           | Isem l-vintat      | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|---------------------|----------------------------------------------------------------------------------------------|---------------|--------------------|--------|-----------------------------|----------------|
| Il-Polonja          | Adamed Sp. z o.o.<br>Pieńków 149<br>05-152 Czosnów k. Warszawy<br>Poland                     | Desloratadina | Desada             | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| Il-Polonja          | Adamed Sp. z o.o.<br>Pieńków 149<br>05-152 Czosnów k. Warszawy<br>Poland                     | Desloratadina | Hitaxa Fast        | 2,5 mg | Pillola li tinħall fil-halq | Użu orali      |
| Il-Polonja          | Adamed Sp. z o.o.<br>Pieńków 149<br>05-152 Czosnów k. Warszawy<br>Poland                     | Desloratadina | Hitaxa             | 2,5 mg | Pillola li tinħall fil-halq | Użu orali      |
| Il-Polonja          | Adamed Sp. z o.o.<br>Pieńków 149<br>05-152 Czosnów k. Warszawy<br>Poland                     | Desloratadina | Hitaxa             | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| Il-Polonja          | Aflofarm Farmacja Polska Sp. z o.o.<br>ul. Partyzancka 133/151<br>95-200 Pabianice<br>Poland | Desloratadina | Teslor             | 5 mg   | Pillola miksjja b'rita      | Użu orali      |
| Il-Polonja          | Aflofarm Farmacja Polska Sp. z o.o.<br>ul. Partyzancka 133/151<br>95-200 Pabianice<br>Poland | Desloratadina | Teslor fast        | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| Il-Polonja          | Aflofarm Farmacja Polska Sp. z o.o.<br>ul. Partyzancka 133/151<br>95-200 Pabianice<br>Poland | Desloratadina | Teslor fast junior | 2,5 mg | Pillola li tinħall fil-halq | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                            | INN                        | Isem Ivvintat          | Qawwa          | Għamla farmaċewtika                  | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------|----------------------------|------------------------|----------------|--------------------------------------|----------------|
| Il-Polonja           | Apotex Europe B.V.<br>Darwinweg 20<br>NL 2333 CR Leiden<br>Netherlands          | Trimetazidina              | ApoTrimet PR           | 35 mg          | Pillola li terhi il-mediċina bil-mod | Użu orali      |
| Il-Polonja           | Bio-Profil Polska Sp. z o.o.<br>Trakt Lubelski 135<br>04-790 Warszawa<br>Poland | Desloratadina              | Desloratadine Peseri   | 5 mg           | Pillola miksjija b'rita              | Użu orali      |
| Il-Polonja           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany     | Valsartan/idroklorotijazid | Valsartan HCT Fair-Med | 320 mg/12,5 mg | Pillola miksjija b'rita              | Użu orali      |
| Il-Polonja           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany     | Valsartan/idroklorotijazid | Valsartan HCT Fair-Med | 320 mg/25 mg   | Pillola miksjija b'rita              | Użu orali      |
| Il-Polonja           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany     | Ċiprofloksacina            | Ciprofloxacin Fair-Med | 250 mg         | Pillola miksjija b'rita              | Użu orali      |
| Il-Polonja           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany     | Ċiprofloksacina            | Ciprofloxacin Fair-Med | 500 mg         | Pillola miksjija b'rita              | Użu orali      |
| Il-Polonja           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany     | Irbesartan                 | Irbesartan Fair-Med    | 75 mg          | Pillola miksjija b'rita              | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                        | INN                         | Isem Ivvintat           | Qawwa          | Għamla farmaċewtika                            | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------|-----------------------------|-------------------------|----------------|------------------------------------------------|----------------|
| Il-Polonja           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan                  | Irbesartan Fair-Med     | 150 mg         | Pillola miksija b'rita                         | Użu orali      |
| Il-Polonja           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan                  | Irbesartan Fair-Med     | 300 mg         | Pillola miksija b'rita                         | Użu orali      |
| Il-Polonja           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/idroklorotijazid | Irbesartan HCT Fair-Med | 150 mg/12,5 mg | Pillola miksija b'rita                         | Użu orali      |
| Il-Polonja           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/idroklorotijazid | Irbesartan HCT Fair-Med | 300 mg/12,5 mg | Pillola miksija b'rita                         | Użu orali      |
| Il-Polonja           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/idroklorotijazid | Irbesartan HCT Fair-Med | 300 mg/25 mg   | Pillola miksija b'rita                         | Użu orali      |
| Il-Polonja           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/idroklorotijazid  | Valsartan HCT Fair-Med  | 160 mg/12,5 mg | Pillola miksija b'rita                         | Użu orali      |
| Il-Polonja           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Venlafaksina                | VENLAFAXINE FAIR-MED    | 37,5 mg        | Kapsula li terfi l-medikazzjoni bil-mod, iebes | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                        | INN                    | Isem Ivvintat          | Qawwa  | Għamla farmaċewtika                        | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------------------|------------------------|------------------------|--------|--------------------------------------------|----------------|
| Il-Polonja           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                 | Venlafaksina           | VENLAFAXINE FAIR-MED   | 75 mg  | Kapsula li terhi l-medicina bil-mod, iebša | Użu orali      |
| Il-Polonja           | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                 | Venlafaksina           | VENLAFAXINE FAIR-MED   | 150 mg | Kapsula li terhi l-medicina bil-mod, iebša | Użu orali      |
| Il-Polonja           | Generics (UK) Ltd<br>Station Close, Porters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Kandesartan ċileksetil | Kangen                 | 8 mg   | Pillola                                    | Użu orali      |
| Il-Polonja           | Generics (UK) Ltd<br>Station Close, Porters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Kandesartan ċileksetil | Kangen                 | 16 mg  | Pillola                                    | Użu orali      |
| Il-Polonja           | Labormed-Pharma, SA<br>Theodor Pallady, 44B<br>032266 Bucharest<br>Romania                  | Desloratadina          | Desloratadine Labormed | 2,5 mg | Pillola li tinħall fil-halq                | Użu orali      |
| Il-Polonja           | Labormed-Pharma, SA<br>Theodor Pallady, 44B<br>032266 Bucharest<br>Romania                  | Desloratadina          | Desloratadine Labormed | 5 mg   | Pillola li tinħall fil-halq                | Użu orali      |
| Il-Polonja           | Medicplast Polska Sp. z o.o<br>ul. Wólczyńska 232<br>01-919 Warszawa<br>Poland              | Desloratadina          | Desalergo              | 5 mg   | Pillola miksiġa b'rita                     | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                            | INN           | Isem Ivvintat   | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------|---------------|-----------------|--------|-----------------------------|----------------|
| Il-Polonja           | Medicoplast Polska Sp. z o.o<br>ul. Wólczyńska 232<br>01-919 Warszawa<br>Poland | Desloratadina | Desalergo       | 2,5 mg | Pillola li tinhall fil-halq | Użu orali      |
| Il-Polonja           | Medicoplast Polska Sp. z o.o<br>ul. Wólczyńska 232<br>01-919 Warszawa<br>Poland | Desloratadina | Desalergo       | 5 mg   | Pillola li tinhall fil-halq | Użu orali      |
| Il-Polonja           | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland        | Valsartan     | Valsartan Orion | 40 mg  | Pillola miksija b'rita      | Użu orali      |
| Il-Polonja           | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland        | Valsartan     | Valsartan Orion | 80 mg  | Pillola miksija b'rita      | Użu orali      |
| Il-Polonja           | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland        | Valsartan     | Valsartan Orion | 160 mg | Pillola miksija b'rita      | Użu orali      |
| Il-Polonja           | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland        | Valsartan     | Valsartan Orion | 320 mg | Pillola miksija b'rita      | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                        | INN               | Isem Ivvintat        | Qawwa  | Għamla farmaċewtika                       | Mnejn jingħata |
|----------------------|-------------------------------------------------------------------------------------------------------------|-------------------|----------------------|--------|-------------------------------------------|----------------|
| Il-Polonja           | Peseri Trading Limited<br>20 Queen Frederica Street<br>El-Greco House, office 301<br>1066 Nicosia<br>Cyprus | Desloratadina     | Desloratadine Peseri | 2,5 mg | Pillola li tinħall fil-halq               | Użu orali      |
| Il-Polonja           | Peseri Trading Limited<br>20 Queen Frederica Street<br>El-Greco House, office 301<br>1066 Nicosia<br>Cyprus | Desloratadina     | Desloratadine Peseri | 5 mg   | Pillola li tinħall fil-halq               | Użu orali      |
| Il-Polonja           | Ranbaxy (Poland) Sp. z o.o.<br>Kubickiego 11<br>02-954 Warszawa<br>Poland                                   | Acidu alendroniku | Alendran 70          | 70 mg  | Pillola                                   | Użu orali      |
| Il-Polonja           | Sandoz GmbH<br>Biochemiestrasse 10<br>A-6250 Kundl<br>Austria                                               | Trimetażidina     | Dimesar              | 35 mg  | Pillola li terhi il-medi-<br>ċina bil-mod | Użu orali      |
| Il-Polonja           | S-Lab Sp. z o.o.<br>ul. Kielczowska 2<br>55-095 Mirków<br>Poland                                            | Desloratadina     | Suprodeslon          | 5 mg   | Pillola miksija b'rita                    | Użu orali      |
| Il-Polonja           | S-Lab Sp. z o.o.<br>ul. Kielczowska 2<br>55-095 Mirków<br>Poland                                            | Desloratadina     | Suprodeslon          | 2,5 mg | Pillola li tinħall fil-halq               | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                      | INN           | Isem Ivvintat         | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------------------------------|---------------|-----------------------|--------|-----------------------------|----------------|
| Il-Polonja          | S-Lab Sp. z o.o.<br>ul. Kielczowska 2<br>55-095 Mirków<br>Poland                                          | Desloratadina | Suprodeslon           | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| Il-Polonja          | SymPhar Sp. z o.o.<br>ul. Włoska 1<br>00-777 Warszawa<br>Poland                                           | Desloratadina | Symdes                | 5 mg   | Pillola miksijsja b'rita    | Użu orali      |
| Il-Polonja          | Tactica Pharmaceuticals sp. z o.o.<br>ul. Bankowa 4<br>44-100 Gliwice<br>Poland                           | Desloratadina | Goldesin              | 5 mg   | Pillola miksijsja b'rita    | Użu orali      |
| Il-Polonja          | US Pharmacia Sp. z o.o.<br>ul. Ziębicka 40<br>50-507 Wrocław<br>Poland                                    | Desloratadina | Aleric Deslo          | 5 mg   | Pillola miksijsja b'rita    | Użu orali      |
| Il-Polonja          | US Pharmacia Sp. z o.o.<br>ul. Ziębicka 40<br>50-507 Wrocław<br>Poland                                    | Desloratadina | Aleric Deslo          | 2,5 mg | Pillola li tinħall fil-halq | Użu orali      |
| Il-Polonja          | US Pharmacia Sp. z o.o.<br>ul. Ziębicka 40<br>50-507 Wrocław<br>Poland                                    | Desloratadina | Aleric Deslo Active   | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| Il-Polonja          | Wockhardt UK Limited<br>Ash Road North<br>Wrexham Industrial Estate<br>Wrexham LL13 9UF<br>United Kingdom | Klopidoqrel   | Clopidogrel Wockhardt | 75 mg  | Pillola miksijsja b'rita    | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                            | INN                  | Isem Ivvintat                | Qawwa          | Għamla farmaċewtika                               | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------------------------------------|----------------------|------------------------------|----------------|---------------------------------------------------|----------------|
| Il-Portugall        | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Acidu alendroniku    | Ácido alendrónico Accord     | 70 mg          | Pillola                                           | Użu orali      |
| Il-Portugall        | Alkaloid – INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana – Črnuče<br>Slovenia                                     | Ċefpodosima          | Cefpodoxima Alkaloid         | 200 mg         | Pillola                                           | Użu orali      |
| Il-Portugall        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                    | Tramadol/paracetamol | Tramadol + Paracetamol Brown | 37,5 mg/325 mg | Pillola miksija b'rita                            | Użu orali      |
| Il-Portugall        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                    | Trimetazidina        | Trimetazidina Brown          | 35 mg          | Pillola li terhi il-medi-<br>čina b'mod modifikat | Użu orali      |
| Il-Portugall        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                    | Exxitalopram         | Escitalopram Brown           | 10 mg          | Pillola miksija b'rita                            | Użu orali      |
| Il-Portugall        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                    | Exxitalopram         | Escitalopram Brown           | 15 mg          | Pillola miksija b'rita                            | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                                                                                           | INN          | Isem Ivvintat       | Qawwa | Għamla farmaċewtika     | Mnejn jingħata |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---------------------|-------|-------------------------|----------------|
| Il-Portugall        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                                                                                   | Exxitalopram | Escitalopram Brown  | 5 mg  | Pillola miksjija b'rita | Użu orali      |
| Il-Portugall        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                                                                                   | Exxitalopram | Escitalopram Brown  | 20 mg | Pillola miksjija b'rita | Użu orali      |
| Il-Portugall        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                                                                                   | Ebastina     | Ebastina Brown      | 10 mg | Pillola miksjija b'rita | Użu orali      |
| Il-Portugall        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                                                                                   | Ebastina     | Ebastina Brown      | 20 mg | Pillola miksjija b'rita | Użu orali      |
| Il-Portugall        | Daquimed – Comércio de Produtos Farmacêuticos, S.A.<br>Av. Associação Comercial e Industrial de Gondomar, 330 – Zona Industrial da Portelinha<br>4510-688 Fânzeres<br>Portugal | Ketjapina    | Quetiapina Daquimed | 25 mg | Pillola miksjija b'rita | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                                                                                           | INN       | Isem Ivvintat       | Qawwa  | Għamla farmaċewtika    | Mnejn jingħata |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---------------------|--------|------------------------|----------------|
| Il-Portugall         | Daquimed – Comércio de Produtos Farmacêuticos, S.A.<br>Av. Associação Comercial e Industrial de Gondomar, 330 – Zona Industrial da Portelinha<br>4510-688 Fânzeres<br>Portugal | Ketjapina | Quetiapina Daquimed | 100 mg | Pillola miksija b'rita | Użu orali      |
| Il-Portugall         | Daquimed – Comércio de Produtos Farmacêuticos, S.A.<br>Av. Associação Comercial e Industrial de Gondomar, 330 – Zona Industrial da Portelinha<br>4510-688 Fânzeres<br>Portugal | Ketjapina | Quetiapina Daquimed | 150 mg | Pillola miksija b'rita | Użu orali      |
| Il-Portugall         | Daquimed – Comércio de Produtos Farmacêuticos, S.A.<br>Av. Associação Comercial e Industrial de Gondomar, 330 – Zona Industrial da Portelinha<br>4510-688 Fânzeres<br>Portugal | Ketjapina | Quetiapina Daquimed | 200 mg | Pillola miksija b'rita | Użu orali      |
| Il-Portugall         | Daquimed – Comércio de Produtos Farmacêuticos, S.A.<br>Av. Associação Comercial e Industrial de Gondomar, 330 – Zona Industrial da Portelinha<br>4510-688 Fânzeres<br>Portugal | Ketjapina | Quetiapina Daquimed | 300 mg | Pillola miksija b'rita | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                | INN                              | Isem Ivvintat                                | Qawwa                           | Għamla farmaċewtika     | Mnejn jingħata |
|----------------------|-------------------------------------------------------------------------------------|----------------------------------|----------------------------------------------|---------------------------------|-------------------------|----------------|
| Il-Portugall         | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal | Levodopa/karbidopa/<br>entakapon | Levodopa + Carbidopa + Entacapona<br>Generis | 50 mg/12,5 mg/<br>200 mg        | Pillola miksjija b'rita | Użu orali      |
| Il-Portugall         | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal | Levodopa/karbidopa/<br>entakapon | Levodopa + Carbidopa + Entacapona<br>Generis | 75 mg/<br>18,75 mg/<br>200 mg   | Pillola miksjija b'rita | Użu orali      |
| Il-Portugall         | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal | Levodopa/karbidopa/<br>entakapon | Levodopa + Carbidopa + Entacapona<br>Generis | 100 mg/25 mg/<br>200 mg         | Pillola miksjija b'rita | Użu orali      |
| Il-Portugall         | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal | Levodopa/karbidopa/<br>entakapon | Levodopa + Carbidopa + Entacapona<br>Generis | 125 mg/<br>31,250 mg/<br>200 mg | Pillola miksjija b'rita | Użu orali      |
| Il-Portugall         | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal | Levodopa/karbidopa/<br>entakapon | Levodopa + Carbidopa + Entacapona<br>Generis | 150 mg/<br>37,5 mg/200 mg       | Pillola miksjija b'rita | Użu orali      |
| Il-Portugall         | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal | Levodopa/karbidopa/<br>entakapon | Levodopa + Carbidopa + Entacapona<br>Generis | 175 mg/<br>43,75 mg/<br>200 mg  | Pillola miksjija b'rita | Użu orali      |
| Il-Portugall         | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal | Levodopa/karbidopa/<br>entakapon | Levodopa + Carbidopa + Entacapona<br>Generis | 200 mg/50 mg/<br>200 mg         | Pillola miksjija b'rita | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                                                                      | INN               | Isem Ivvintat              | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------------------|--------|-----------------------------|----------------|
| Il-Portugall        | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal                                                                       | Entakapon         | Entacapona Generis         | 200 mg | Pillola miksja b'rita       | Użu orali      |
| Il-Portugall        | Labesfal, Genéricos, S.A.<br>Av. Dr. Afonso Costa, n° 1370<br>3465-051 Campo de Besteiros<br>Portugal                                                     | Desloratadina     | Desloratadina Labesfal OD  | 2,5 mg | Pillola li tinħall fil-halq | Użu orali      |
| Il-Portugall        | Labesfal, Genéricos, S.A.<br>Av. Dr. Afonso Costa, n° 1370<br>3465-051 Campo de Besteiros<br>Portugal                                                     | Desloratadina     | Desloratadina Labesfal OD  | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| Il-Portugall        | Labesfal, Genéricos, S.A.<br>Av. Dr. Afonso Costa, n° 1370<br>3465-051 Campo de Besteiros<br>Portugal                                                     | Ácido alendroniku | Ácido alendrónico Labesfal | 70 mg  | Pillola                     | Użu orali      |
| Il-Portugall        | Laboratórios Anova – Produtos Farmacêuticos, Lda.<br>Rua Doutor António Loureiro Borges<br>Edifício Arquiparque 1, R/C Esqº<br>1499-016 Algés<br>Portugal | Donepezil         | Donepezilo Anova           | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| Il-Portugall        | Laboratórios Anova – Produtos Farmacêuticos, Lda.<br>Rua Doutor António Loureiro Borges<br>Edifício Arquiparque 1, R/C Esqº<br>1499-016 Algés<br>Portugal | Donepezil         | Donepezilo Anova           | 10 mg  | Pillola li tinħall fil-halq | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                                                                      | INN          | Isem Ivvintat        | Qawwa   | Għamla farmaċewtika                        | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|----------------------|---------|--------------------------------------------|----------------|
| Il-Portugall         | Laboratórios Anova – Produtos Farmacêuticos, Lda.<br>Rua Doutor António Loureiro Borges<br>Edifício Arquiparque 1, R/C Esqº<br>1499-016 Algés<br>Portugal | Esomeprazol  | Esomeprazol Anova    | 20 mg   | Kapsula gastro-reżistenti, iebša           | Użu orali      |
| Il-Portugall         | Laboratórios Anova – Produtos Farmacêuticos, Lda.<br>Rua Doutor António Loureiro Borges<br>Edifício Arquiparque 1, R/C Esqº<br>1499-016 Algés<br>Portugal | Esomeprazol  | Esomeprazol Anova    | 40 mg   | Kapsula gastro-reżistenti, iebša           | Użu orali      |
| Il-Portugall         | Laboratórios Azevedos – Indústria Farmacêutica, S.A.<br>Edifícios Azevedos – Estrada Nacional 117-2, Alfragide<br>2614-504 Amadora<br>Portugal            | Venlafaksina | Venlafaxina Azevedos | 37,5 mg | Kapsula li terhi l-medicina bil-mod, iebša | Użu orali      |
| Il-Portugall         | Laboratórios Azevedos – Indústria Farmacêutica, S.A.<br>Edifícios Azevedos – Estrada Nacional 117-2, Alfragide<br>2614-504 Amadora<br>Portugal            | Venlafaksina | Venlafaxina Azevedos | 75 mg   | Kapsula li terhi l-medicina bil-mod, iebša | Użu orali      |
| Il-Portugall         | Laboratórios Azevedos – Indústria Farmacêutica, S.A.<br>Edifícios Azevedos – Estrada Nacional 117-2, Alfragide<br>2614-504 Amadora<br>Portugal            | Venlafaksina | Venlafaxina Azevedos | 150 mg  | Kapsula li terhi l-medicina bil-mod, iebša | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                                                       | INN           | Isem Ivvintat          | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------|---------------|------------------------|--------|-----------------------------|----------------|
| Il-Portugall        | Laboratórios Basi – Indústria Farmacêutica, S.A<br>Parque Industrial Manuel Lourenço<br>Ferreira, Lote 15<br>3450-232 Mortágua<br>Portugal | Flukonazol    | Fluconazol Basi        | 50 mg  | Kapsula                     | Użu orali      |
| Il-Portugall        | Laboratórios Basi – Indústria Farmacêutica, S.A<br>Parque Industrial Manuel Lourenço<br>Ferreira, Lote 15<br>3450-232 Mortágua<br>Portugal | Flukonazol    | Fluconazol Basi        | 150 mg | Kapsula                     | Użu orali      |
| Il-Portugall        | Laboratórios Basi – Indústria Farmacêutica, S.A<br>Parque Industrial Manuel Lourenço<br>Ferreira, Lote 15<br>3450-232 Mortágua<br>Portugal | Flukonazol    | Fluconazol Basi        | 200 mg | Kapsula                     | Użu orali      |
| Il-Portugall        | Labormed-Pharma, SA<br>Theodor Pallady, 44B<br>032266 Bucharest<br>Romania                                                                 | Desloratadina | Desloratadina Labormed | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| Il-Portugall        | Labormed-Pharma, SA<br>Theodor Pallady, 44B<br>032266 Bucharest<br>Romania                                                                 | Desloratadina | Desloratadina Labormed | 2,5 mg | Pillola li tinħall fil-halq | Użu orali      |
| Il-Portugall        | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16 0PF<br>United Kingdom                                    | Ċefpodoksima  | Cefpodoxima Lupin      | 200 mg | Pillola miksija b'rita      | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                                          | INN           | Isem Ivvintat       | Qawwa | Għamla farmaċewtika              | Mnein jingħata |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------|---------------|---------------------|-------|----------------------------------|----------------|
| Il-Portugall         | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Ezomeprazol   | Esomeprazol Mylan   | 20 mg | Kapsula gastro-režistenti, iebsa | Użu orali      |
| Il-Portugall         | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Ezomeprazol   | Esomeprazol Mylan   | 40 mg | Kapsula gastro-režistenti, iebsa | Użu orali      |
| Il-Portugall         | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Atorvastatina | Atorvastatina Anova | 10 mg | Pillola miksjija b'rita          | Użu orali      |
| Il-Portugall         | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Atorvastatina | Atorvastatina Anova | 20 mg | Pillola miksjija b'rita          | Użu orali      |
| Il-Portugall         | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Atorvastatina | Atorvastatina Anova | 40 mg | Pillola miksjija b'rita          | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                                          | INN           | Isem Ivvintat       | Qawwa | Għamla farmaċewtika                          | Mnein jingħata |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------|---------------|---------------------|-------|----------------------------------------------|----------------|
| Il-Portugall         | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Atorvastatina | Atorvastatina Anova | 80 mg | Pillola miksija b'rita                       | Użu orali      |
| Il-Portugall         | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Donepezil     | Donepezilo Mylan    | 5 mg  | Pillola li tinħall fil-halq                  | Użu orali      |
| Il-Portugall         | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Donepezil     | Donepezilo Mylan    | 10 mg | Pillola li tinħall fil-halq                  | Użu orali      |
| Il-Portugall         | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Trimetazidina | Trimetazidina Mylan | 35 mg | Pillola li terhi il-mediċina b'mod modifikat | Użu orali      |
| Il-Portugall         | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Kandesartan   | Candesartan Mylan   | 4 mg  | Pillola                                      | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                                          | INN           | Isem Ivvinat         | Qawwa | Għamla farmaċewtika         | Mnejn jingħata |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------|---------------|----------------------|-------|-----------------------------|----------------|
| Il-Portugall        | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Kandesartan   | Candesartan Mylan    | 8 mg  | Pillola                     | Użu orali      |
| Il-Portugall        | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Kandesartan   | Candesartan Mylan    | 16 mg | Pillola                     | Użu orali      |
| Il-Portugall        | Mylan, Lda.<br>Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C – 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Kandesartan   | Candesartan Mylan    | 32 mg | Pillola                     | Użu orali      |
| Il-Portugall        | Peseri Trading Limited<br>20 Queen Frederica Street<br>El-Greco House, office 301<br>1066 Nicosia<br>Cyprus                   | Desloratadina | Desloratadina Peseri | 5 mg  | Pillola miksija b'rita      | Użu orali      |
| Il-Portugall        | Peseri Trading Limited<br>20 Queen Frederica Street<br>El-Greco House, office 301<br>1066 Nicosia<br>Cyprus                   | Desloratadina | Desloratadina Peseri | 5 mg  | Pillola li tinħall fil-halq | Użu orali      |

| Stat Membru (il-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                                                                                                     | INN           | Isem Ivvinat             | Qawwa  | Għamla farmaċewtika                          | Mnejn jingħata |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|--------------------------|--------|----------------------------------------------|----------------|
| Il-Portugall         | Peseri Trading Limited<br>20 Queen Frederica Street<br>EL-Greco House, office 301<br>1066 Nicosia<br>Cyprus                                                                              | Desloratadina | Desloratadina Peseri     | 2,5 mg | Pillola li tinħall fil-halq                  | Użu orali      |
| Il-Portugall         | Pharmakern Portugal – Produtos Farmacêuticos, Sociedade Unipessoal, Lda.<br>Edifício Atlas II, Av. José Gomes Ferreira, N.º 11 – 3.º, Sala 31 – Miraflores<br>1495-139 Algés<br>Portugal | Trimetazidina | Trimetazidina Pharmakern | 35 mg  | Pillola li terhi il-mediċina b'mod modifikat | Użu orali      |
| Il-Portugall         | Ratiopharm – Comércio e Indústria de Produtos Farmacêuticos, Lda.<br>Lagoas Park, Edifício 5 A, Piso 2<br>2740-245 Porto Salvo<br>Portugal                                               | Desloratadina | Desloratadina Ratiopharm | 2,5 mg | Pillola li tinħall fil-halq                  | Użu orali      |
| Il-Portugall         | Ratiopharm – Comércio e Indústria de Produtos Farmacêuticos, Lda.<br>Lagoas Park, Edifício 5 A, Piso 2<br>2740-245 Porto Salvo<br>Portugal                                               | Desloratadina | Desloratadina Ratiopharm | 5 mg   | Pillola li tinħall fil-halq                  | Użu orali      |
| Il-Portugall         | Sandoz Farmaceutica Lda.<br>Avenida Professor Doutor Cavaco Silva, n. 10E Taguspark<br>2740-255 Porto Salvo<br>Portugal                                                                  | Trimetazidina | Trimetazidina Itraxel    | 35 mg  | Pillola li terhi il-mediċina bil-mod         | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                                              | INN           | Isem Ivvinat                         | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------------------------------------------------------|---------------|--------------------------------------|--------|-----------------------------|----------------|
| Il-Portugall        | Teva Pharma – Produtos Farmacêuticos, Lda.<br>Edifício Tejo, Rua Quinta do Pinheiro,<br>16 – 6º<br>2790-143 Carnaxide<br>Portugal | Desloratadina | Desloratadina Teva                   | 2,5 mg | Pillola li tinħall fil-halq | Użu orali      |
| Il-Portugall        | Teva Pharma – Produtos Farmacêuticos, Lda.<br>Edifício Tejo, Rua Quinta do Pinheiro,<br>16 – 6º<br>2790-143 Carnaxide<br>Portugal | Desloratadina | Desloratadina Teva                   | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| Ir-Rumanija         | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France                                                         | Exxitalopram  | SAVANDRA 5 mg comprimate<br>filmate  | 5 mg   | Pillola miksjija b'rita     | Użu orali      |
| Ir-Rumanija         | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France                                                         | Exxitalopram  | SAVANDRA 10 mg comprimate<br>filmate | 10 mg  | Pillola miksjija b'rita     | Użu orali      |
| Ir-Rumanija         | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France                                                         | Exxitalopram  | SAVANDRA 15 mg comprimate<br>filmate | 15 mg  | Pillola miksjija b'rita     | Użu orali      |
| Ir-Rumanija         | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France                                                         | Exxitalopram  | SAVANDRA 20 mg comprimate<br>filmate | 20 mg  | Pillola miksjija b'rita     | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                                   | INN           | Isem Ivinat                                             | Qawwa    | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|------------------------------------------------------------------------------------------------------------------------|---------------|---------------------------------------------------------|----------|------------------------|----------------|
| Ir-Rumanija         | Alkaloid – INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana – Črnuče<br>Slovenia                                            | Čefpodoksima  | Forexo 200 mg comprimate filmate                        | 200 mg   | Pillola                | Użu orali      |
| Ir-Rumanija         | Alvogen IPCo S.ar.l.<br>Rue Heienhaff 5<br>L-1736 Senningerberg<br>Lussemburgu                                         | Desloratadina | Desloratadina Alvogen 5 mg comprimate filmate           | 5 mg     | Pillola miksija b'rita | Użu orali      |
| Ir-Rumanija         | Dr. Reddy's Laboratories Romania SRL<br>71st-73rd Nicolae Caramfil, Floor 5,<br>Space 10, Sector 1, Bucuresti, Romania | Levetiracetam | Levetiracetam Dr. Reddy's, 250 mg, comprimate filmate   | 250 mg   | Pillola                | Użu orali      |
| Ir-Rumanija         | Dr. Reddy's Laboratories Romania SRL<br>71st-73rd Nicolae Caramfil, Floor 5,<br>Space 10, Sector 1, Bucuresti, Romania | Levetiracetam | Levetiracetam Dr. Reddy's, 500 mg, comprimate filmate   | 500 mg   | Pillola                | Użu orali      |
| Ir-Rumanija         | Dr. Reddy's Laboratories Romania SRL<br>71st-73rd Nicolae Caramfil, Floor 5,<br>Space 10, Sector 1, Bucuresti, Romania | Levetiracetam | Levetiracetam Dr. Reddy's, 750 mg, comprimate filmate   | 750 mg   | Pillola                | Użu orali      |
| Ir-Rumanija         | Dr. Reddy's Laboratories Romania SRL<br>71st-73rd Nicolae Caramfil, Floor 5,<br>Space 10, Sector 1, Bucuresti, Romania | Levetiracetam | Levetiracetam Dr. Reddy's, 1 000 mg, comprimate filmate | 1 000 mg | Pillola                | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                                   | INN                              | Isem Ivvintat                                           | Qawwa         | Għamla farmaċewtika              | Mnejn jingħata |
|---------------------|------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------|---------------|----------------------------------|----------------|
| Ir-Rumanija         | Dr. Reddy's Laboratories Romania SRL<br>71st-73rd Nicolae Caramfil, Floor 5,<br>Space 10, Sector 1, Bucuresti, Romania | Telmisartan                      | Telmisartan Dr. Reddy's 40 mg<br>comprimate             | 40 mg         | Pillola                          | Użu orali      |
| Ir-Rumanija         | Dr. Reddy's Laboratories Romania SRL<br>71st-73rd Nicolae Caramfil, Floor 5,<br>Space 10, Sector 1, Bucuresti, Romania | Telmisartan                      | Telmisartan Dr. Reddy's 80 mg<br>comprimate             | 80 mg         | Pillola                          | Użu orali      |
| Ir-Rumanija         | Dr. Reddy's Laboratories Romania SRL<br>71st-73rd Nicolae Caramfil, Floor 5,<br>Space 10, Sector 1, Bucuresti, Romania | Telmisartan/<br>idroklorotijazid | Telmisartan HCT Dr. Reddy's 40 mg/12,5 mg<br>comprimate | 40 mg/12,5 mg | Pillola                          | Użu orali      |
| Ir-Rumanija         | Dr. Reddy's Laboratories Romania SRL<br>71st-73rd Nicolae Caramfil, Floor 5,<br>Space 10, Sector 1, Bucuresti, Romania | Telmisartan/<br>idroklorotijazid | Telmisartan HCT Dr. Reddy's 80 mg/12,5 mg<br>comprimate | 80 mg/12,5 mg | Pillola                          | Użu orali      |
| Ir-Rumanija         | Dr. Reddy's Laboratories Romania SRL<br>71st-73rd Nicolae Caramfil, Floor 5,<br>Space 10, Sector 1, Bucuresti, Romania | Telmisartan/<br>idroklorotijazid | Telmisartan HCT Dr. Reddy's 80 mg/25 mg<br>comprimate   | 80 mg/25 mg   | Pillola                          | Użu orali      |
| Ir-Rumanija         | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom                            | Ezomeprazol manjeżju             | Esomeprazol Mylan 20 mg capsule<br>gastrorezistente     | 20 mg         | Kapsula gastro-rezistenti, iebsa | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                        | INN                    | Isem Ivvintat                                         | Qawwa  | Għamla farmaċewtika                   | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------------------|------------------------|-------------------------------------------------------|--------|---------------------------------------|----------------|
| Ir-Rumanija          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Esomeprazol manjeżju   | Esomeprazol Mylan 40 mg capsule<br>gastrorezistente   | 40 mg  | Kapsula gastro-reżis-<br>tenti, iebsa | Użu orali      |
| Ir-Rumanija          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezil kloridrat    | Donepezil Mylan 5 mg comprimate<br>orodispersabile    | 5 mg   | Pillola li tinħall fil-halq           | Użu orali      |
| Ir-Rumanija          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezil kloridrat    | Donepezil Mylan 10 mg compri-<br>mate orodispersabile | 10 mg  | Pillola li tinħall fil-halq           | Użu orali      |
| Ir-Rumanija          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Repaglinid             | Repaglinida Generics 0,5 mg com-<br>primate           | 0,5 mg | Pillola                               | Użu orali      |
| Ir-Rumanija          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Repaglinid             | Repaglinida Generics 1 mg com-<br>primate             | 1 mg   | Pillola                               | Użu orali      |
| Ir-Rumanija          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Repaglinid             | Repaglinida Generics 2 mg com-<br>primate             | 2 mg   | Pillola                               | Użu orali      |
| Ir-Rumanija          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Kandesartan ċileksetil | Candesartan Mylan 4 mg compri-<br>mate                | 4 mg   | Pillola                               | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                         | INN                     | Isem Ivvintat                                            | Qawwa  | Għamla farmaċewtika                          | Mnejn jingħata |
|----------------------|----------------------------------------------------------------------------------------------|-------------------------|----------------------------------------------------------|--------|----------------------------------------------|----------------|
| Ir-Rumanija          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom  | Kandesartan ċileksetil  | Candesartan Mylan 8 mg comprimate                        | 8 mg   | Pillola                                      | Użu orali      |
| Ir-Rumanija          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom  | Kandesartan ċileksetil  | Candesartan Mylan 16 mg comprimate                       | 16 mg  | Pillola                                      | Użu orali      |
| Ir-Rumanija          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom  | Benžoat tar-rizatriptan | Rizatriptan Mylan 5 mg comprimate orodispersabile        | 5 mg   | Pillola li tinħall fil-halq                  | Użu orali      |
| Ir-Rumanija          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom  | Benžoat tar-rizatriptan | Rizatriptan Mylan 10 mg comprimate orodispersabile       | 10 mg  | Pillola li tinħall fil-halq                  | Użu orali      |
| Ir-Rumanija          | Glenmark Pharmaceuticals s.r.o.<br>Hvězdova 1716/2b<br>14078 Praha 4<br>Czech Republic       | Trimetazidina           | Apstar 35 mg<br>Comprimete cu eliberare prelungită       | 35 mg  | Pillola li terhi il-mediċina b'mod modifikat | Użu orali      |
| Ir-Rumanija          | Labormed Pharma SA<br>Bd. Theodor Pallady nr. 44 B<br>032266, sector 3, București<br>România | Desloratadina           | Desloratadine Labormed 2,5 mg comprimate orodispersabile | 2,5 mg | Pillola li tinħall fil-halq                  | Użu orali      |
| Ir-Rumanija          | Labormed Pharma SA<br>Bd. Theodor Pallady nr. 44 B<br>032266, sector 3, București<br>România | Desloratadina           | Desloratadine Labormed 5 mg comprimate orodispersabile   | 5 mg   | Pillola li tinħall fil-halq                  | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                 | INN           | Isem l-vintat                                                        | Qawwa  | Għamla farmaċewtika                          | Mnejn jingħata |
|----------------------|------------------------------------------------------------------------------------------------------|---------------|----------------------------------------------------------------------|--------|----------------------------------------------|----------------|
| Ir-Rumanija          | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                               | Trimetazidina | Trimetazidina Mylan 35 mg comprimati filmati cu eliberare prelungita | 35 mg  | Pillola li terhi il-medicina bil-mod         | Użu orali      |
| Ir-Rumanija          | Sandoz Pharma Services SRL<br>Calea Floreasca Street<br>No 169 A, district 2<br>Bucharest<br>Romania | Trimetazidina | Trimeluzine Limited 35 mg comprimati filmati cu eliberare modificata | 35 mg  | Pillola li terhi il-medicina b'mod modificat | Użu orali      |
| Ir-Rumanija          | STADA Hemofarm S.R.L.<br>Calea Torontalului km 6 – PITT<br>300633 Timișoara<br>Romania               | Entakapon     | ENTANIDA 200 comprimate filmate                                      | 200 mg | Pillola miksjia b'rita                       | Użu orali      |
| Ir-Rumanija          | Teva Pharmaceuticals S.R.L.<br>Str. Domnița Ruxandra nr. 12, parter,<br>sector 2, București, România | Desloratadina | Desloratadina Teva 5 mg comprimati orodispersibili                   | 5 mg   | Pillola li tinħall fil-halq                  | Użu orali      |
| Ir-Rumanija          | Torrent Pharma SRL<br>Str. Stirbei Voda nr. 36<br>et. 2, biroul A, sector 1<br>Bucharest<br>Romania  | Irbesartan    | Irbesartan Torrent 75 mg comprimati filmati                          | 75 mg  | Pillola miksjia b'rita                       | Użu orali      |
| Ir-Rumanija          | Torrent Pharma SRL<br>Str. Stirbei Voda nr. 36<br>et. 2, biroul A, sector 1<br>Bucharest<br>Romania  | Irbesartan    | Irbesartan Torrent 150 mg comprimati filmati                         | 150 mg | Pillola miksjia b'rita                       | Użu orali      |

| Stat Membru (fl-EEA)    | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                | INN                                                | Isem Ivvintat                                                           | Qawwa          | Għamla farmaċewtika    | Mnejn jingħata |
|-------------------------|-----------------------------------------------------------------------------------------------------|----------------------------------------------------|-------------------------------------------------------------------------|----------------|------------------------|----------------|
| Ir-Rumanija             | Torrent Pharma SRL<br>Str. Stirbei Voda nr. 36<br>et. 2, biroul A, sector 1<br>Bucharest<br>Romania | Irbesartan                                         | Irbesartan Torrent 300 mg comprimate filmate                            | 300 mg         | Pillola miksija b'rita | Użu orali      |
| Ir-Rumanija             | Torrent Pharma SRL<br>Str. Stirbei Voda nr. 36<br>et. 2, biroul A, sector 1<br>Bucharest<br>Romania | Irbesartan/idroklorotiazid<br>jażid oclorothiazide | Irbesartan Torrent Hidrochlorotiazida<br>150/12,5 mg comprimate filmate | 150 mg/12,5 mg | Pillola miksija b'rita | Użu orali      |
| Ir-Rumanija             | Torrent Pharma SRL<br>Str. Stirbei Voda nr. 36<br>et. 2, biroul A, sector 1<br>Bucharest<br>Romania | Irbesartan/idroklorotiazid                         | Irbesartan Torrent Hidrochlorotiazida<br>300/12,5 mg comprimate filmate | 300 mg/12,5 mg | Pillola miksija b'rita | Użu orali      |
| Ir-Rumanija             | Torrent Pharma SRL<br>Str. Stirbei Voda nr. 36<br>et. 2, biroul A, sector 1<br>Bucharest<br>Romania | Irbesartan/idroklorotiazid                         | Irbesartan Torrent Hidrochlorotiazida<br>300/25 mg comprimate filmate   | 300 mg/25 mg   | Pillola miksija b'rita | Użu orali      |
| Ir-Repubblika Slovakkja | Alkaloid – INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana – Črnuče<br>Slovenia                         | Čefpodoksima                                       | FOREXO 200 mg filmom obalené<br>tablety                                 | 200 mg         | Pillola miksija b'rita | Użu orali      |
| Ir-Repubblika Slovakkja | Alvogen IPCo S.à.r.l.<br>Rue Heienhaff 5<br>1736 Senningerberg<br>Lussemburgu                       | Desloratadina                                      | Dezloratadin Alvogen 5 mg filmom obalené<br>tablety                     | 5 mg           | Pillola miksija b'rita | Użu orali      |

| Stat Membru (l-EEA)     | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                        | INN                     | Isem l-vintat                                    | Qawwa | Għamla farmaċewtika                          | Mnejn jingħata |
|-------------------------|---------------------------------------------------------------------------------------------|-------------------------|--------------------------------------------------|-------|----------------------------------------------|----------------|
| Ir-Repubblika Slovakkja | Genericon s.r.o.,<br>Anny Letenské 1108/15,<br>120 00 Praha 2 – Vinohrady<br>Czech Republic | Desloratadina           | GESLORA 5 mg                                     | 5 mg  | Pillola miksija b'rita                       | Użu orali      |
| Ir-Repubblika Slovakkja | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezil kloridrat     | Donepezil Mylan 5 mg orodispergovateľné tablety  | 5 mg  | Pillola li tinhall fil-halq                  | Użu orali      |
| Ir-Repubblika Slovakkja | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezil kloridrat     | Donepezil Mylan 10 mg orodispergovateľné tablety | 10 mg | Pillola li tinhall fil-halq                  | Użu orali      |
| Ir-Repubblika Slovakkja | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Benzoat tar-rizatriptan | Rizatriptan Mylan 10 mg                          | 10 mg | Pillola li tinhall fil-halq                  | Użu orali      |
| Ir-Repubblika Slovakkja | Glenmark Pharmaceuticals s.r.o.<br>Hvězdova 1716/2b<br>14078 Praha 4<br>Czech Republic      | Trimetazidina           | Apstar 35 mg tablety s predĺženým uvoľňovaním    | 35 mg | Pillola li terhi il-medičina b'mod modifikat | Użu orali      |
| Ir-Repubblika Slovakkja | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                      | Trimetazidina           | Trimetazidin Mylan 35 mg                         | 35 mg | Pillola li terhi il-medičina b'mod modifikat | Użu orali      |
| Ir-Repubblika Slovakkja | SVUS Pharma a.s.<br>Smetanovo nábřeží 1238/20a<br>500 02 Hradec Králové<br>Czech Republic   | Desloratadina           | LOTERA 5 mg filmom obalené tablety               | 5 mg  | Pillola miksija b'rita                       | Użu orali      |

| Stat Membru (fl-EEA)    | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                        | INN                  | Isem Ivvintat                                          | Qawwa  | Għamla farmaċewtika              | Mnein jingħata |
|-------------------------|---------------------------------------------------------------------------------------------|----------------------|--------------------------------------------------------|--------|----------------------------------|----------------|
| Ir-Repubblika Slovakkja | Teva Pharmaceuticals Slovakia s.r.o.<br>Teslova 26<br>821 02 Bratislava<br>Slovak Republic  | Desloratadina        | Dezloratadin Teva OROTAB 2,5 mg                        | 2,5 mg | Pillola li tinħall fil-halq      | Użu orali      |
| Ir-Repubblika Slovakkja | Teva Pharmaceuticals Slovakia s.r.o.<br>Teslova 26<br>821 02 Bratislava<br>Slovak Republic  | Desloratadina        | Dezloratadin Teva OROTAB 5 mg                          | 5 mg   | Pillola li tinħall fil-halq      | Użu orali      |
| Is-Slovenja             | Alkaloid – INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana – Črnuče<br>Slovenia                 | Čefpodoksima         | Trexodo 200 mg filmsko obložene tablete                | 200 mg | Pillola miksija b'rita           | Użu orali      |
| Is-Slovenja             | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Ežomeprazol manježju | Esomeprazol Mylan 20 mg trde gastrorezistentne kapsule | 20 mg  | Kapsula gastro-režistenti, iebša | Użu orali      |
| Is-Slovenja             | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Ežomeprazol manježju | Esomeprazol Mylan 40 mg trde gastrorezistentne kapsule | 40 mg  | Kapsula gastro-režistenti, iebša | Użu orali      |
| Is-Slovenja             | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezil kloridrat  | Donepezil Mylan 5 mg orodisperzibbli tablete           | 5 mg   | Pillola li tinħall fil-halq      | Użu orali      |
| Is-Slovenja             | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezil kloridrat  | Donepezil Mylan 10 mg orodisperzibbli tablete          | 10 mg  | Pillola li tinħall fil-halq      | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                                                  | INN                       | Isem Ivvintat                                                                                      | Qawwa          | Għamla farmaċewtika                  | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------------------------------------------------------------------------------------|----------------|--------------------------------------|----------------|
| Is-Slovenja          | Lek farmacevtska družba d.d.<br>Verovškova 57<br>1526 Ljubljana<br>Slovenia                                                           | Trimetazidina kloridra    | Trimeluzine 35 mg tablete s podaljšanim sproščanjem                                                | 35 mg          | Pillola li terhi il-mediċina bil-mod | Użu orali      |
| Spanja               | Accord Healthcare, S.L.U.<br>Moll de Barcelona s/n. World Trade Center. Edifici Est 6 <sup>a</sup> planta,<br>8039 Barcelona<br>Spain | Metoklopramid             | METOCLOPRAMIDA ACCORD<br>10 mg COMPRIMIDOS EFG                                                     | 10 mg          | Pillola                              | Użu orali      |
| Spanja               | Apotex Europe B.V.<br>Darwinweg 20<br>NL 2333 CR Leiden<br>Netherlands                                                                | Desloratadina             | DESLOTATADINA APOTEX 5 mg<br>COMPRIMIDOS RECUBIERTOS<br>CON PELICULA EFG                           | 5 mg           | Pillola miksjia b'rita               | Użu orali      |
| Spanja               | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                                          | Ebastina                  | EBASTINA BROWN 10 mg COM-<br>PRIMIDOS BUCODISPERSABLES<br>EFG                                      | 10 mg          | Pillola li tinħall fil-halq          | Użu orali      |
| Spanja               | Farmalider, S.A.<br>Aragoneses 15<br>28108 Madrid<br>Spain                                                                            | Valsartan/idroklorotiazid | VALSARTAN/HIDROCLOROTIAZIDA CODRAMOL 160 MG/12,5 mg<br>COMPRIMIDOS RECUBIERTOS<br>CON PELICULA EFG | 160 mg/12,5 mg | Pillola miksjia b'rita               | Użu orali      |
| Spanja               | Farmalider, S.A.<br>Aragoneses 15<br>28108 Madrid<br>Spain                                                                            | Valsartan/idroklorotiazid | VALSARTAN/HIDROCLOROTIAZIDA CODRAMOL 160/25 mg<br>COMPRIMIDOS RECUBIERTOS<br>CON PELICULA EFG      | 160 mg/25 mg   | Pillola miksjia b'rita               | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                  | INN                        | Isem Ivvintat                                                                             | Qawwa          | Għamla farmaċewtika    | Mnein jingħata |
|----------------------|-------------------------------------------------------------------------------------------------------|----------------------------|-------------------------------------------------------------------------------------------|----------------|------------------------|----------------|
| Spanja               | Farmalider, S.A.<br>Aragoneses 15<br>28108 Madrid<br>Spain                                            | Valsartan/idroklorotijazid | VALSARTAN/HIDROKLOROTIAZIDA CODRAMOL 320/12,5 mg COMPRIMIDOS RECUBIERTOS CON PELÍCULA EFG | 320 mg/12,5 mg | Pillola miksija b'rita | Użu orali      |
| Spanja               | Farmalider, S.A.<br>Aragoneses 15<br>28108 Madrid<br>Spain                                            | Valsartan/idroklorotijazid | VALSARTAN/HIDROKLOROTIAZIDA CODRAMOL 320/25 mg COMPRIMIDOS RECUBIERTOS CON PELÍCULA EFG   | 320 mg/25 mg   | Pillola miksija b'rita | Użu orali      |
| Spanja               | Farmalider, S.A.<br>Aragoneses 15<br>28108 Madrid<br>Spain                                            | Valsartan/idroklorotijazid | VALSARTAN/HIDROKLOROTIAZIDA CODRAMOL 80/12,5 mg COMPRIMIDOS RECUBIERTOS CON PELÍCULA EFG  | 80 mg/12,5 mg  | Pillola miksija b'rita | Użu orali      |
| Spanja               | Laboratorios Combix, S.L.U.<br>C/Badajoz 2, Edificio 2<br>Pozuelo de Alarcon<br>Madrid 28223<br>Spain | Desloratadina              | DESLOTATADINA COMBIX 5 mg COMPRIMIDOS RECUBIERTOS CON PELÍCULA EFG                        | 5 mg           | Pillola miksija b'rita | Użu orali      |
| Spanja               | Laboratorios Combix, S.L.U.<br>C/Badajoz 2, Edificio 2<br>Pozuelo de Alarcon<br>Madrid 28223<br>Spain | Desloratadina              | DESLOTATADINA FLAS COMBIX 5 mg COMPRIMIDOS BUCODISPERSABLES EFG                           | 5 mg           | Pillola miksija b'rita | Użu orali      |
| Spanja               | Laboratorios Combix, S.L.U.<br>C/Badajoz 2, Edificio 2<br>Pozuelo de Alarcon<br>Madrid 28223<br>Spain | Exxitalopram               | ESCITALOPRAM COMBIX 10 mg COMPRIMIDOS RECUBIERTOS CON PELÍCULA EFG                        | 10 mg          | Pillola miksija b'rita | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                  | INN               | Isem Ivvintat                                                                           | Qawwa | Għamla farmaċewtika         | Mnejn jingħata |
|----------------------|-------------------------------------------------------------------------------------------------------|-------------------|-----------------------------------------------------------------------------------------|-------|-----------------------------|----------------|
| Spanja               | Laboratorios Combix, S.L.U.<br>C/Badajoz 2, Edificio 2<br>Pozuelo de Alarcon<br>Madrid 28223<br>Spain | Exxitalopram      | ESCITALOPRAM COMBIX 15 mg<br>COMPRIMIDOS RECUBIERTOS<br>CON PELICULA EFG                | 15 mg | Pillola miksija b'rita      | Użu orali      |
| Spanja               | Laboratorios Combix, S.L.U.<br>C/Badajoz 2, Edificio 2<br>Pozuelo de Alarcon<br>Madrid 28223<br>Spain | Exxitalopram      | ESCITALOPRAM COMBIX 20 mg<br>COMPRIMIDOS RECUBIERTOS<br>CON PELICULA EFG                | 20 mg | Pillola miksija b'rita      | Użu orali      |
| Spanja               | Laboratorios Combix, S.L.U.<br>C/Badajoz 2, Edificio 2<br>Pozuelo de Alarcon<br>Madrid 28223<br>Spain | Exxitalopram      | ESCITALOPRAM COMBIX 5 mg<br>COMPRIMIDOS RECUBIERTOS<br>CON PELICULA EFG                 | 5 mg  | Pillola miksija b'rita      | Użu orali      |
| Spanja               | Laboratorios Ranbaxy, S. L. U.<br>Paseig de Gracia 9<br>7a Pl<br>Barcelona 08007<br>Spain             | Acidu alendroniku | ACIDO ALENDRONICO SEMANAL<br>RANBAXY 70 mg COMPRIMIDOS<br>EFG                           | 70 mg | Pillola                     | Użu orali      |
| Spanja               | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5º Planta<br>8038 Barcelona<br>Spain                         | Donepezil         | DONEPEZILO FLAS MYLAN<br>PHARMACEUTICALS 10 mg<br>COMPRIMIDOS BUCODISPERSA-<br>BLES EFG | 10 mg | Pillola li tinħall fil-halq | Użu orali      |
| Spanja               | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5º Planta<br>8038 Barcelona<br>Spain                         | Donepezil         | DONEPEZILO FLAS MYLAN<br>PHARMACEUTICALS 5 mg COM-<br>PRIMIDOS BUCODISPERSABLES<br>EFG  | 5 mg  | Pillola li tinħall fil-halq | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                          | INN         | Isem Ivvintat                                                   | Qawwa  | Għamla farmaċewtika              | Mnejn jingħata |
|----------------------|-------------------------------------------------------------------------------|-------------|-----------------------------------------------------------------|--------|----------------------------------|----------------|
| Spanja               | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5° Planta<br>8038 Barcelona<br>Spain | Ezomeprazol | ESOMEPRAZOL MYLAN 20 mg<br>CAPSULAS GASTORRESISTENTES EFG       | 20 mg  | Kapsula gastro-reżistenti, iebsa | Użu orali      |
| Spanja               | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5° Planta<br>8038 Barcelona<br>Spain | Ezomeprazol | ESOMEPRAZOL MYLAN 40 mg<br>CAPSULAS GASTORRESISTENTES EFG       | 40 mg  | Kapsula gastro-reżistenti, iebsa | Użu orali      |
| Spanja               | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5° Planta<br>8038 Barcelona<br>Spain | Repaglinid  | REPAGLINIDA MYLAN 0,5 mg<br>COMPRIMIDOS EFG                     | 0,5 mg | Pillola                          | Użu orali      |
| Spanja               | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5° Planta<br>8038 Barcelona<br>Spain | Repaglinid  | REPAGLINIDA MYLAN 1 mg<br>COMPRIMIDOS EFG                       | 1 mg   | Pillola                          | Użu orali      |
| Spanja               | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5° Planta<br>8038 Barcelona<br>Spain | Repaglinid  | REPAGLINIDA MYLAN 2 mg<br>COMPRIMIDOS EFG                       | 2 mg   | Pillola                          | Użu orali      |
| Spanja               | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5° Planta<br>8038 Barcelona<br>Spain | Rizatriptan | RIZATRIPTAN MAX MYLAN<br>10 mg COMPRIMIDOS BUCODISPERSABLES EFG | 10 mg  | Pillola li tinħall fil-halq      | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                      | INN               | Isem l-ivvintat                                                                              | Qawwa          | Għamla farmaċewtika         | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------------------------------|-------------------|----------------------------------------------------------------------------------------------|----------------|-----------------------------|----------------|
| Spanja              | PENSA PHARMA, S.A.U<br>Jorge Comín (médico pediatra)<br>3 – bajos<br>46015 – Valencia (Valencia)<br>Spain | Ácido alendroniku | ACIDO ALENDRONICO SEMANAL<br>PENSA 70 mg COMPRIMIDOS EFG                                     | 70 mg          | Pillola                     | Użu orali      |
| Spanja              | Pharmagenus, S.A.,<br>Avda. Camí Real, 51-57,<br>08184 Palau-solita i Plegamans (Barcelona)<br>Spain      | Desloratadina     | DESLOTATADINA PHARMAGENUS 2,5 mg COMPRIMIDOS BUCODISPERSABLES EFG                            | 2,5 mg         | Pillola li tinħall fil-halq | Użu orali      |
| Spanja              | Pharmagenus, S.A.,<br>Avda. Camí Real, 51-57,<br>08184 Palau-solita i Plegamans (Barcelona)<br>Spain      | Desloratadina     | DESLOTATADINA PHARMAGENUS 5 mg COMPRIMIDOS BUCODISPERSABLES EFG                              | 5 mg           | Pillola li tinħall fil-halq | Użu orali      |
| Spanja              | Teva Pharma S.L.U.<br>C/Anabel Segura, 11<br>Edificio Albatros B, 1ª planta<br>Madrid 28108<br>Spain      | Desloratadina     | DESLOTATADINA TEVA 5 mg COMPRIMIDOS BUCODISPERSABLES EFG                                     | 5 mg           | Pillola li tinħall fil-halq | Użu orali      |
| Spanja              | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                       | Irbesartan        | IRBESARTAN/HIDROCLOROTIAZIDA WELDING 150 mg/12,5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG | 150 mg/12,5 mg | Pillola miksjia b'rita      | Użu orali      |
| Spanja              | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                       | Irbesartan        | IRBESARTAN/HIDROCLOROTIAZIDA WELDING 300 mg/12,5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG | 300 mg/12,5 mg | Pillola miksjia b'rita      | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                            | INN                     | Isem Ivvintat                                                                              | Qawwa        | Għamla farmaċewtika    | Mnejn jingħata |
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| Spanja              | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                             | Irbesartan              | IRBESARTAN/HIDROKLOROTIAZIDA WELDING 300 mg/25 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG | 300 mg/25 mg | Pillola miksija b'rita | Użu orali      |
| L-Iżvezja           | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Acidu alendroniku       | Alendronat Accord Veckotablett                                                             | 70 mg        | Pillola                | Użu orali      |
| L-Iżvezja           | Alternova A/S<br>Lodshusvej 11<br>DK-4230 Skælskør<br>Denmark                                                   | Klindamicina kloridrata | Clindamycin Alternova                                                                      | 150 mg       | Kapsula, iebsa         | Użu orali      |
| L-Iżvezja           | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                     | Flukonazol              | Fluconazol Bluefish                                                                        | 50 mg        | Kapsula, iebsa         | Użu orali      |
| L-Iżvezja           | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                     | Flukonazol              | Fluconazol Bluefish                                                                        | 150 mg       | Kapsula, iebsa         | Użu orali      |
| L-Iżvezja           | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                     | Flukonazol              | Fluconazol Bluefish                                                                        | 200 mg       | Kapsula, iebsa         | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                        | INN                 | Isem Ivvintat     | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------------------|---------------------|-------------------|--------|-----------------------------|----------------|
| L-I Żvezja           | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezil kloridrat | Donezil           | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| L-I Żvezja           | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezil kloridrat | Donezil           | 10 mg  | Pillola li tinħall fil-halq | Użu orali      |
| L-I Żvezja           | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                  | Donepezil           | Donepezil Mylan   | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| L-I Żvezja           | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                  | Donepezil           | Donepezil Mylan   | 10 mg  | Pillola li tinħall fil-halq | Użu orali      |
| L-I Żvezja           | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                  | Rizatriptan         | Rizatriptan Mylan | 10 mg  | Pillola li tinħall fil-halq | Użu orali      |
| L-I Żvezja           | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                  | Repaglinid          | Repaglinid Mylan  | 0,5 mg | Pillola                     | Użu orali      |
| L-I Żvezja           | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                  | Repaglinid          | Repaglinid Mylan  | 1 mg   | Pillola                     | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                     | INN         | Isem Ivvintat     | Qawwa | Għamla farmaċewtika              | Mnein jingħata |
|---------------------|--------------------------------------------------------------------------|-------------|-------------------|-------|----------------------------------|----------------|
| L-I Żvezja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden               | Repaglinid  | Repaglinid Mylan  | 2 mg  | Pillola                          | Użu orali      |
| L-I Żvezja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden               | Ezomeprazol | Esomeprazol Mylan | 20 mg | Kapsula gastro-reżistenti, iebša | Użu orali      |
| L-I Żvezja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden               | Ezomeprazol | Esomeprazol Mylan | 40 mg | Kapsula gastro-reżistenti, iebša | Użu orali      |
| L-I Żvezja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden               | Eletriptan  | Eletriptan Mylan  | 20 mg | Pillola miksjija b'rita          | Użu orali      |
| L-I Żvezja          | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden               | Eletriptan  | Eletriptan Mylan  | 40 mg | Pillola miksjija b'rita          | Użu orali      |
| L-I Żvezja          | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland | Valsartan   | Valsartan Orion   | 40 mg | Pillola miksjija b'rita          | Użu orali      |
| L-I Żvezja          | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland | Valsartan   | Valsartan Orion   | 80 mg | Pillola miksjija b'rita          | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                            | INN               | Isem Ivvintat                                         | Qawwa   | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------------------------------------|-------------------|-------------------------------------------------------|---------|------------------------|----------------|
| L-Iżvezja           | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                                        | Valsartan         | Valsartan Orion                                       | 160 mg  | Pillola miksija b'rita | Użu orali      |
| L-Iżvezja           | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                                        | Valsartan         | Valsartan Orion                                       | 320 mg  | Pillola miksija b'rita | Użu orali      |
| L-Iżvezja           | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>United Kingdom      | Acidu alendroniku | Alendronat Ranbaxy<br>Veckotablett 70 mg<br>tabletter | 70 mg   | Pillola                | Użu orali      |
| L-Iżvezja           | Stada Arzneimittel AG<br>Stadastrasse 2-18<br>DE-61118 Bad Vilbel<br>Germany                                    | Entakapon         | Entakapon STADA                                       | 200 mg  | Pillola miksija b'rita | Użu orali      |
| L-Olanda            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol         | Ropinirol Accord 5 mg, filmom-hulde tabletten         | 5 mg    | Pillola miksija b'rita | Użu orali      |
| L-Olanda            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol         | Ropinirol Accord 0,25 mg filmom-hulde tabletten       | 0,25 mg | Pillola miksija b'rita | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                            | INN                     | Isem Ivvintat                                           | Qawwa  | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|-----------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------------------------------------|--------|------------------------|----------------|
| L-Olanda            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol               | Ropinirol Accord 0,5 mg filmomhulde tabletten           | 0,5 mg | Pillola miksija b'rita | Użu orali      |
| L-Olanda            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol               | Ropinirol Accord 1 mg filmomhulde tabletten             | 1 mg   | Pillola miksija b'rita | Użu orali      |
| L-Olanda            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol               | Ropinirol Accord 2 mg filmomhulde tabletten             | 2 mg   | Pillola miksija b'rita | Użu orali      |
| L-Olanda            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Acidu alendroniku       | Alendroninezuur Accord 10 mg Tabletten                  | 10 mg  | Pillola                | Użu orali      |
| L-Olanda            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Acidu alendroniku       | Alendroninezuur Accord 70 mg Tabletten                  | 70 mg  | Pillola                | Użu orali      |
| L-Olanda            | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Metoklopramid kloridrat | Metoclopramidemonohydrochloride Accord 10 mg, Tabletten | 10 mg  | Pillola                | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                              | INN             | Isem Ivvintat                                                                  | Qawwa   | Għamla farmaċewtika                        | Mnejn jinghata |
|----------------------|-------------------------------------------------------------------------------------------------------------------|-----------------|--------------------------------------------------------------------------------|---------|--------------------------------------------|----------------|
| L-Olanda             | Alembic Pharmaceuticals Europe Limited<br>Palazzo Pietro Stiges, 103, Strait Street<br>VLT 1436 Valletta<br>Malta | Venlafaksina    | Venlafaxine HCl Retard Alembic<br>37,5 mg, capsule met verlengde afgifte, hard | 37,5 mg | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| L-Olanda             | Alembic Pharmaceuticals Europe Limited<br>Palazzo Pietro Stiges, 103, Strait Street<br>VLT 1436 Valletta<br>Malta | Venlafaksina    | Venlafaxine HCl Retard Alembic<br>75 mg, capsule met verlengde afgifte, hard   | 75 mg   | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| L-Olanda             | Alembic Pharmaceuticals Europe Limited<br>Palazzo Pietro Stiges, 103, Strait Street<br>VLT 1436 Valletta<br>Malta | Venlafaksina    | Venlafaxine HCl Retard Alembic<br>150 mg, capsule met verlengde afgifte, hard  | 150 mg  | Kapsula li terhi l-medicina bil-mod, iebsa | Użu orali      |
| L-Olanda             | Brown & Burk UK, Ltd.<br>5, Maryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                       | Ebastina        | Ebastine BB 10 mg orodispergeerbare tabletten                                  | 10 mg   | Pillola li tinhall fil-halq                | Użu orali      |
| L-Olanda             | Centrafarm B.V.<br>Nieuwe Donk 3<br>4879 AC Etten Leur<br>The Netherlands                                         | Entakapon       | Entacapone CF 200 mg, filmomhulde tablet                                       | 200 mg  | Pillola miksija b'rita                     | Użu orali      |
| L-Olanda             | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                       | Ċiprofloksacina | Ciprofloxacin Fair-Med 250 mg, filmomhulde tabletten                           | 250 mg  | Pillola miksija b'rita                     | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                        | INN                        | Isem Ivvintat                                                     | Qawwa          | Għamla farmaċewtika                        | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------|----------------------------|-------------------------------------------------------------------|----------------|--------------------------------------------|----------------|
| L-Olanda             | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Ċiprofloksaċina            | Ciprofloxacin Fair-Med 500 mg,<br>filmomhulde tabletten           | 500 mg         | Pillola miksija b'rita                     | Użu orali      |
| L-Olanda             | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Ċiprofloksaċina            | Ciprofloxacin Fair-Med 750 mg,<br>filmomhulde tabletten           | 750 mg         | Pillola miksija b'rita                     | Użu orali      |
| L-Olanda             | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/idroklorotijazid | Valsartan/HCTZ Fair-Med 160 mg/<br>12,5 mg, filmomhulde tabletten | 160 mg/12,5 mg | Pillola miksija b'rita                     | Użu orali      |
| L-Olanda             | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/idroklorotijazid | Valsartan/HCTZ Fair-Med 320 mg/<br>12,5 mg, filmomhulde tabletten | 320 mg/12,5 mg | Pillola miksija b'rita                     | Użu orali      |
| L-Olanda             | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/idroklorotijazid | Valsartan/HCTZ Fair-Med 320 mg/<br>25 mg, filmomhulde tabletten   | 320 mg/25 mg   | Pillola miksija b'rita                     | Użu orali      |
| L-Olanda             | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Venlafaksina               | Venlafaxin Fair-Med 37,5 mg capsules met verlengde afgifte, hard  | 37,5 mg        | Kapsula li terhi l-medicina bil-mod, iebes | Użu orali      |
| L-Olanda             | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Venlafaksina               | Venlafaxin Fair-Med 75 mg capsules met verlengde afgifte, hard    | 75 mg          | Kapsula li terhi l-medicina bil-mod, iebes | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                       | INN               | Isem Ivvintat                                                    | Qawwa  | Għamla farmaċewtika                         | Mnejn jingħata |
|----------------------|------------------------------------------------------------------------------------------------------------|-------------------|------------------------------------------------------------------|--------|---------------------------------------------|----------------|
| L-Olanda             | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                | Venlafaksina      | Venlafaxine Fair-Med 150 mg capsules met verlengde afgifte, hard | 150 mg | Kapsula li terhi l-medicina bil-mod, iebssa | Użu orali      |
| L-Olanda             | Mylan B.V.<br>Dieselweg 25<br>3752 LB Bunschoten<br>The Netherlands                                        | Ezomeprazol       | Esomeprazol Mylan 20 mg, maag-sapresistente capsules, hard       | 20 mg  | Kapsula gastro-rezistenti, iebssa           | Użu orali      |
| L-Olanda             | Mylan B.V.<br>Dieselweg 25<br>3752 LB Bunschoten<br>The Netherlands                                        | Ezomeprazol       | Esomeprazol Mylan 40 mg, maag-sapresistente capsules, hard       | 40 mg  | Kapsula gastro-rezistenti, iebssa           | Użu orali      |
| L-Olanda             | Mylan B.V.<br>Dieselweg 25<br>3752 LB Bunschoten<br>The Netherlands                                        | Rizatriptan       | Rizatriptan SmeltTab Mylan 5 mg, orodispergeerbare tabletten     | 5 mg   | Pillola li tinhall fil-halq                 | Użu orali      |
| L-Olanda             | Mylan B.V.<br>Dieselweg 25<br>3752 LB Bunschoten<br>The Netherlands                                        | Rizatriptan       | Rizatriptan SmeltTab Mylan 10 mg, orodispergeerbare tabletten    | 10 mg  | Pillola li tinhall fil-halq                 | Użu orali      |
| L-Olanda             | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>United Kingdom | Acidu alendroniku | Alendroninezuur 70 Ranbaxy, tabletten 70 mg                      | 70 mg  | Pillola                                     | Użu orali      |
| L-Olanda             | Sandoz B.V.<br>Veluwezoom 22<br>1327 AH Almere<br>The Netherlands                                          | Klonazepam        | Clonazepam Sandoz 0,5 mg, tabletten                              | 0,5 mg | Pillola                                     | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                      | INN           | Isem Ivvintat                                                         | Qawwa  | Għamla farmaċewtika         | Mnein jingħata |
|----------------------|-------------------------------------------------------------------------------------------|---------------|-----------------------------------------------------------------------|--------|-----------------------------|----------------|
| L-Olanda             | Sandoz B.V.<br>Veluwezoom 22<br>1327 AH Almere<br>The Netherlands                         | Klonazepam    | Clonazepam Sandoz 2 mg, tabletten                                     | 2 mg   | Pillola                     | Użu orali      |
| L-Olanda             | Sandoz B.V.<br>Veluwezoom 22<br>1327 AH Almere<br>The Netherlands                         | Klobazam      | Clobazam Sandoz 10 mg, tabletten                                      | 10 mg  | Pillola                     | Użu orali      |
| L-Olanda             | Teva Nederland B.V.<br>Swensweg 5<br>2031 GA Haarlem<br>The Netherlands                   | Desloratadina | Desloratadine Smelttablet 2,5 mg<br>Teva, orodispergeerbare tabletten | 2,5 mg | Pillola li tinħall fil-halq | Użu orali      |
| L-Olanda             | Teva Nederland B.V.<br>Swensweg 5<br>2031 GA Haarlem<br>The Netherlands                   | Desloratadina | Desloratadine Smelttablet 5 mg Teva, orodispergeerbare tabletten      | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| L-Olanda             | TioFarma b.v.<br>Benjamin Franklinstraat 5-10<br>3261 LW Oud-Beyerland<br>The Netherlands | Klonazepam    | Clonazepam TioFarma 0,5 mg tabletten, tabletten                       | 0,5 mg | Pillola                     | Użu orali      |
| L-Olanda             | TioFarma b.v.<br>Benjamin Franklinstraat 5-10<br>3261 LW Oud-Beyerland<br>The Netherlands | Klonazepam    | Clonazepam TioFarma 2 mg tabletten, tabletten                         | 2 mg   | Pillola                     | Użu orali      |
| L-Olanda             | TioFarma b.v.<br>Benjamin Franklinstraat 5-10<br>3261 LW Oud-Beyerland<br>The Netherlands | Klobazam      | Clobazam TioFarma 10 mg, tabletten                                    | 10 mg  | Pillola                     | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                      | INN                         | Isem l-vintat                                                               | Qawwa          | Għamla farmaċewtika    | Mnejn jingħata |
|----------------------|-------------------------------------------------------------------------------------------|-----------------------------|-----------------------------------------------------------------------------|----------------|------------------------|----------------|
| L-Olanda             | TioFarma b.v.<br>Benjamin Franklinstraat 5-10<br>3261 LW Oud-Beyerland<br>The Netherlands | Klobazam                    | Clobazam TioFarma 20 mg, tabletten                                          | 20 mg          | Pillola                | Użu orali      |
| L-Olanda             | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                        | irbesartan                  | Irbesartan Torrent 75 mg filmomhulde tabletten                              | 75 mg          | Pillola miksija b'rita | Użu orali      |
| L-Olanda             | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                        | irbesartan                  | Irbesartan Torrent 150 mg filmomhulde tabletten                             | 150 mg         | Pillola miksija b'rita | Użu orali      |
| L-Olanda             | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                        | irbesartan                  | Irbesartan Torrent 300 mg filmomhulde tabletten                             | 300 mg         | Pillola miksija b'rita | Użu orali      |
| L-Olanda             | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                        | Irbesartan/idroklorotijazid | Irbesartan Hydrochlorothiazide Torrent 150 mg/12,5 mg filmomhulde tabletten | 150 mg/12,5 mg | Pillola miksija b'rita | Użu orali      |
| L-Olanda             | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                        | Irbesartan/idroklorotijazid | Irbesartan Hydrochlorothiazide Torrent 300 mg/12,5 mg filmomhulde tabletten | 300 mg/12,5 mg | Pillola miksija b'rita | Użu orali      |
| L-Olanda             | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                        | Irbesartan/idroklorotijazid | Irbesartan Hydrochlorothiazide Torrent 300 mg/25 mg filmomhulde tabletten   | 300 mg/25 mg   | Pillola miksija b'rita | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                                                   | INN        | Isem l-vintat                                 | Qawwa   | Għamla farmaċewtika    | Mnejn jingħata |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------|------------|-----------------------------------------------|---------|------------------------|----------------|
| L-Olanda             | Unichem Laboratories Ltd.<br>Studio 8B Ard Gaoithe Commercial Centre, Business Park<br>Cashel Road Clonmel,<br>Co Tipperary<br>Ireland | irbesartan | Irbesartan Unichem 150 mg film-coated tablets | 150 mg  | Pillola miksija b'rita | Użu orali      |
| L-Olanda             | Unichem Laboratories Ltd.<br>Studio 8B Ard Gaoithe Commercial Centre, Business Park<br>Cashel Road Clonmel,<br>Co Tipperary<br>Ireland | irbesartan | Irbesartan Unichem 300 mg film-coated tablets | 300 mg  | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit        | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom                        | Ropinirol  | Ropinirole 0,25 mg film-coated tablets        | 0,25 mg | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit        | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom                        | Ropinirol  | Ropinirole 0,5 mg film-coated tablets         | 0,5 mg  | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit        | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom                        | Ropinirol  | Ropinirole 1 mg film-coated tablets           | 1 mg    | Pillola miksija b'rita | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                            | INN                     | Isem Ivvintat                              | Qawwa | Għamla farmaċewtika    | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------------------------------------|-------------------------|--------------------------------------------|-------|------------------------|----------------|
| Ir-Renju Unit        | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol               | Ropinirole 2 mg film-coated tablets        | 2 mg  | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit        | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Acidu alendroniku       | alendronic acid 10 mg Tablets              | 10 mg | Pillola                | Użu orali      |
| Ir-Renju Unit        | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Acidu alendroniku       | alendronic acid 70 mg Once Daily Tablets   | 70 mg | Pillola                | Użu orali      |
| Ir-Renju Unit        | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Metoklopramid kloridrat | metoclopramide hydrochloride 10 mg tablets | 10 mg | Pillola                | Użu orali      |
| Ir-Renju Unit        | Accord Healthcare Limited<br>Sage House, 319 Pinner Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol               | Ropinirole 5 mg film-coated tablets        | 5 mg  | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit        | Aptil Pharma Limited<br>9th Floor, CP House<br>97-107 Uxbridge Road<br>London W5 5TL<br>United Kingdom          | Flukonazol              | Fluconazole 50 mg capsules                 | 50 mg | Kapsula, iebsa         | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                    | INN                 | Isem l-vintat               | Qawwa  | Għamla farmaċewtika | Mnein jingħata |
|---------------------|---------------------------------------------------------------------------------------------------------|---------------------|-----------------------------|--------|---------------------|----------------|
| Ir-Renju Unit       | Aptil Pharma Limited<br>9th Floor, CP House<br>97-107 Uxbridge Road<br>London W5 5TL<br>United Kingdom  | Flukonazol          | Fluconazole 150 mg capsules | 150 mg | Kapsula, iebsa      | Użu orali      |
| Ir-Renju Unit       | Aptil Pharma Limited<br>9th Floor, CP House<br>97-107 Uxbridge Road<br>London W5 5TL<br>United Kingdom  | Flukonazol          | Fluconazole 200 mg capsules | 200 mg | Kapsula, iebsa      | Użu orali      |
| Ir-Renju Unit       | Auden McKenzie Limited<br>McKenzie House<br>Bury Street, Ruislip<br>Middlesex HA4 7TL<br>United Kingdom | Deksametazon        | Dexamethasone 2 mg Tablets  | 2 mg   | Pillola             | Użu orali      |
| Ir-Renju Unit       | Auden McKenzie Limited<br>McKenzie House<br>Bury Street, Ruislip<br>Middlesex HA4 7TL<br>United Kingdom | Tijamina kloridrata | Tyvera 50 mg Tablets        | 50 mg  | Pillola             | Użu orali      |
| Ir-Renju Unit       | Auden McKenzie Limited<br>McKenzie House<br>Bury Street, Ruislip<br>Middlesex HA4 7TL<br>United Kingdom | Tijamina kloridazon | Tyvera 100 mg Tablets       | 100 mg | Pillola             | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                    | INN                      | Isem l-vintat                                      | Qawwa  | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|---------------------------------------------------------------------------------------------------------|--------------------------|----------------------------------------------------|--------|------------------------|----------------|
| Ir-Renju Unit       | Auden McKenzie Limited<br>McKenzie House<br>Bury Street, Ruislip<br>Middlesex HA4 7TL<br>United Kingdom | Klonazepam               | Clonazepam 500 mcg Tablet                          | 0,5 mg | Pillola                | Użu orali      |
| Ir-Renju Unit       | Auden McKenzie Limited<br>McKenzie House<br>Bury Street, Ruislip<br>Middlesex HA4 7TL<br>United Kingdom | Klonazepam               | Clonazepam 2 mg Tablet                             | 2 mg   | Pillola                | Użu orali      |
| Ir-Renju Unit       | Auden McKenzie Limited<br>McKenzie House<br>Bury Street, Ruislip<br>Middlesex HA4 7TL<br>United Kingdom | Klobazam                 | CLOBAZAM AUDEN 10 mg TA-BLETS                      | 10 mg  | Pillola                | Użu orali      |
| Ir-Renju Unit       | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom            | Fenoksimetil penicillina | Phenoxymethylpenicillin 250 mg Film-coated Tablets | 250 mg | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit       | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom            | Ossalat tal-exxitalopram | Escitalopram 5 mg Film-coated tablets              | 5 mg   | Pillola miksija b'rita | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                         | INN                           | Isem Ivvintat                             | Qawwa  | Għamla farmaċewtika                       | Mnejn jingħata |
|----------------------|----------------------------------------------------------------------------------------------|-------------------------------|-------------------------------------------|--------|-------------------------------------------|----------------|
| Ir-Renju Unit        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Ossalat tal-exxitalo-<br>pram | Escitalopram 10 mg Film-coated<br>tablets | 10 mg  | Pillola miksija b'rita                    | Użu orali      |
| Ir-Renju Unit        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Ossalat tal-exxitalo-<br>pram | Escitalopram 15 mg Film-coated<br>tablets | 15 mg  | Pillola miksija b'rita                    | Użu orali      |
| Ir-Renju Unit        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Ossalat tal-exxitalo-<br>pram | Escitalopram 20 mg Film-coated<br>tablets | 20 mg  | Pillola miksija b'rita                    | Użu orali      |
| Ir-Renju Unit        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Tramadol kloridrat            | Accon 100 mg Prolonged-release<br>tablets | 100 mg | Pillola li terhi il-medi-<br>ċina bil-mod | Użu orali      |
| Ir-Renju Unit        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Tramadol kloridrat            | Accon 150 mg Prolonged-release<br>tablets | 150 mg | Pillola li terhi il-medi-<br>ċina bil-mod | Użu orali      |
| Ir-Renju Unit        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Tramadol kloridrat            | Accon 200 mg Prolonged-release<br>tablets | 200 mg | Pillola li terhi il-medi-<br>ċina bil-mod | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                            | INN           | Isem Ivvintat                            | Qawwa  | Għamla farmaċewtika    | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------------------------------------|---------------|------------------------------------------|--------|------------------------|----------------|
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Valsartan     | Valsartan 40 mg Capsules                 | 40 mg  | Kapsula                | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Valsartan     | Valsartan 80 mg Capsules                 | 80 mg  | Kapsula                | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Valsartan     | Valsartan 160 mg Capsules                | 160 mg | Kapsula                | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Valsartan     | Valsartan 320 mg Capsules                | 320 mg | Kapsula                | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Levetiracetam | Levetiracetam 250 mg film-coated tablets | 250 mg | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Levetiracetam | Levetiracetam 500 mg film-coated tablets | 500 mg | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Levetiracetam | Levetiracetam 750 mg film-coated tablets | 750 mg | Pillola miksija b'rita | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                            | INN           | Isem Ivvintat                              | Qawwa    | Għamla farmaċewtika                                 | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------------------------------------|---------------|--------------------------------------------|----------|-----------------------------------------------------|----------------|
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Levetiracetam | Levetiracetam 1 000 mg film-coated tablets | 1 000 mg | Pillola miksija b'rita                              | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Pioglitazon   | Pioglitazone 15 mg Tablets                 | 15 mg    | Pillola                                             | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Pioglitazon   | Pioglitazone 30 mg Tablets                 | 30 mg    | Pillola                                             | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Pioglitazon   | Pioglitazone 45 mg Tablets                 | 45 mg    | Pillola                                             | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Dipiridamol   | Attia 200 mg Modified Release Capsules     | 200 mg   | Kapsula li terhi il-medicina b'mod modifikat, iebsa | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Telmisartan   | Telmisartan 20 mg Tablets                  | 20 mg    | Pillola                                             | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Telmisartan   | Telmisartan 40 mg Tablets                  | 40 mg    | Pillola                                             | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                            | INN                              | Isem Ivvintat                                            | Qawwa         | Għamla farmaċewtika    | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------------------------------------------|---------------|------------------------|----------------|
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Telmisartan                      | Telmisartan 80 mg Tablets                                | 80 mg         | Pillola                | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Telmisartan/<br>idroklorotijazid | Telmisartan/Hydrochlorothiazide<br>40 mg/12,5 mg Tablets | 40 mg/12,5 mg | Pillola                | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Telmisartan/<br>idroklorotijazid | Telmisartan/Hydrochlorothiazide<br>80 mg/12,5 mg Tablets | 80 mg/12,5 mg | Pillola                | Użu orali      |
| Ir-Renju Unit        | Dr Reddy's Laboratories (UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Telmisartan/<br>idroklorotijazid | Telmisartan/Hydrochlorothiazide<br>80 mg/25 mg Tablets   | 80 mg/25 mg   | Pillola                | Użu orali      |
| Ir-Renju Unit        | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                     | irbesartan                       | Irbesartan 75 mg Film-coated Tablets                     | 75 mg         | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit        | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                     | irbesartan                       | Irbesartan 150 mg Film-coated Tablets                    | 150 mg        | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit        | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                     | irbesartan                       | Irbesartan 300 mg Film-coated Tablets                    | 300 mg        | Pillola miksija b'rita | Użu orali      |

| Stat Membru (l-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                                    | INN                         | Isem l-vintat                                                        | Qawwa          | Għamla farmaċewtika    | Mnejn jingħata |
|---------------------|-------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------------------------|----------------|------------------------|----------------|
| Ir-Renju Unit       | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                             | Irbesartan/idroklorotijazid | Irbesartan/Hydrochlorothiazide<br>150 mg/12,5 mg film-coated tablets | 150 mg/12,5 mg | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit       | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                             | Irbesartan/idroklorotijazid | Irbesartan/Hydrochlorothiazide<br>300 mg/12,5 mg film-coated tablets | 300 mg/12,5 mg | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit       | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                             | Irbesartan/idroklorotijazid | Irbesartan/Hydrochlorothiazide<br>300 mg/25 mg film-coated tablets   | 300 mg/25 mg   | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit       | Fannin (UK) Ltd<br>42-46 Booth Drive<br>Park Farm South<br>Wellingborough<br>Northamptonshire NN8 6GT<br>United Kingdom | Flukonazol                  | Fluconazole 150 mg capsule                                           | 150 mg         | Kapsula, iebsa         | Użu orali      |
| Ir-Renju Unit       | Fannin (UK) Ltd<br>42-46 Booth Drive<br>Park Farm South<br>Wellingborough<br>Northamptonshire NN8 6GT<br>United Kingdom | Feksofenadina               | Fexofenadine 120 mg film-coated tablets                              | 120 mg         | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit       | Fannin (UK) Ltd<br>42-46 Booth Drive<br>Park Farm South<br>Wellingborough<br>Northamptonshire NN8 6GT<br>United Kingdom | Feksofenadina               | Fexofenadine 180 mg film-coated tablets                              | 180 mg         | Pillola miksija b'rita | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq                                                     | INN                 | Isem Ivvintat                                        | Qawwa  | Għamla farmaċewtika         | Mnejn jingħata |
|----------------------|----------------------------------------------------------------------------------------------------------|---------------------|------------------------------------------------------|--------|-----------------------------|----------------|
| Ir-Renju Unit        | FDC Pharma<br>Unit 6, Fulcrum 1, Solent Way<br>Whiteley, Fareham<br>Hampshire PO15 7FE<br>United Kingdom | Amlodipina          | Amlodipine 5 mg Tablets                              | 5 mg   | Pillola                     | Użu orali      |
| Ir-Renju Unit        | FDC Pharma<br>Unit 6, Fulcrum 1, Solent Way<br>Whiteley, Fareham<br>Hampshire PO15 7FE<br>United Kingdom | Amlodipina          | Amlodipine 10 mg Tablets                             | 10 mg  | Pillola                     | Użu orali      |
| Ir-Renju Unit        | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom              | Repaglinid          | Repaglinide Mylan 0,5 mg Tablets                     | 0,5 mg | Pillola                     | Użu orali      |
| Ir-Renju Unit        | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom              | Repaglinid          | Repaglinide Mylan 1 mg Tablets                       | 1 mg   | Pillola                     | Użu orali      |
| Ir-Renju Unit        | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom              | Repaglinid          | Repaglinide Mylan 2 mg Tablets                       | 2 mg   | Pillola                     | Użu orali      |
| Ir-Renju Unit        | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom              | Donepezil kloridrat | Donepezil Hydrochloride 5 mg Orodispersible Tablets  | 5 mg   | Pillola li tinħall fil-halq | Użu orali      |
| Ir-Renju Unit        | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom              | Donepezil kloridrat | Donepezil Hydrochloride 10 mg Orodispersible Tablets | 10 mg  | Pillola li tinħall fil-halq | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                    | INN                          | Isem Ivvintat                                                     | Qawwa                     | Għamla farmaċewtika              | Mnein jingħata |
|----------------------|---------------------------------------------------------------------------------------------------------|------------------------------|-------------------------------------------------------------------|---------------------------|----------------------------------|----------------|
| Ir-Renju Unit        | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom             | Benzoat tar-rizatriptan      | Rizatriptan 10 mg Orodispersible Tablet                           | 10 mg                     | Pillola li tinhall fil-halq      | Użu orali      |
| Ir-Renju Unit        | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom             | Eżomeprazol manjeżju         | Esomeprazole 20 mg Gastro-resistant Capsules, hard                | 20 mg                     | Kapsula gastro-reżistenti, iebsa | Użu orali      |
| Ir-Renju Unit        | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom             | Eżomeprazol manjeżju         | Esomeprazole 40 mg Gastro-resistant Capsules, hard                | 40 mg                     | Kapsula gastro-reżistenti, iebsa | Użu orali      |
| Ir-Renju Unit        | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom             | Levodopa/karbidopa/entakapon | Levodopa/Carbidopa/Entacapone film-coated tablets 150/37,5/200 mg | 150 mg/<br>37,5 mg/200 mg | Pillola miksija b'rita           | Użu orali      |
| Ir-Renju Unit        | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16 0PF<br>United Kingdom | Pantoprazol                  | Pantoprazole 20 mg Gastro-Resistant tablets                       | 20 mg                     | Pillola gastro-reżistenti        | Użu orali      |
| Ir-Renju Unit        | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16 0PF<br>United Kingdom | Pantoprazol                  | Pantoprazole 40 mg Gastro-Resistant tablets                       | 40 mg                     | Pillola gastro-reżistenti        | Użu orali      |
| Ir-Renju Unit        | Morningside Healthcare Limited<br>115 Narborough Road<br>Leicester, LE3 0PA<br>United Kingdom           | Fenoksimeil penicillina      | Phenoxymethylpenicillin 250 mg Film-coated Tablets                | 250 mg                    | Pillola miksija b'rita           | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                          | INN                              | Isem Ivvintat                                                             | Qawwa          | Għamla farmaċewtika                       | Mnejn jingħata |
|----------------------|---------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------------------------|----------------|-------------------------------------------|----------------|
| Ir-Renju Unit        | Morningside Healthcare Limited<br>115 Narborough Road<br>Leicester, LE3 0PA<br>United Kingdom                 | Metformina kloridrata            | Bolamyn/Metabet SR 1 000 mg<br>Prolonged Release Tablets                  | 1 000 mg       | Pillola li terhi il-medi-<br>ċina bil-mod | Użu orali      |
| Ir-Renju Unit        | Niche Generics Limited<br>1 The Cam Centre<br>Wilbury Way, Hitchin<br>Hertfordshire SG4 0TW<br>United Kingdom | irbesartan                       | Irbesartan Niche 150 mg film-<br>coated tablets                           | 150 mg         | Pillola miksija b'rita                    | Użu orali      |
| Ir-Renju Unit        | Niche Generics Limited<br>1 The Cam Centre<br>Wilbury Way, Hitchin<br>Hertfordshire SG4 0TW<br>United Kingdom | irbesartan                       | Irbesartan Niche 150 mg film-<br>coated tablets                           | 150 mg         | Pillola miksija b'rita                    | Użu orali      |
| Ir-Renju Unit        | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>United Kingdom    | Acidu alendroniku                | Alendronic Acid 70 mg Tablets                                             | 70 mg          | Pillola                                   | Użu orali      |
| Ir-Renju Unit        | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                                            | Irbesartan/idrokloroti-<br>jazid | Irbesartan Hydrochlorothiazide<br>150 mg/12,5 mg Film-coated ta-<br>blets | 150 mg/12,5 mg | Pillola miksija b'rita                    | Użu orali      |
| Ir-Renju Unit        | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                                            | Irbesartan/idrokloroti-<br>jazid | Irbesartan Hydrochlorothiazide<br>300 mg/12,5 mg Film-coated ta-<br>blets | 300 mg/12,5 mg | Pillola miksija b'rita                    | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                             | INN                         | Isem l-vintat                                                      | Qawwa        | Għamla farmaċewtika                        | Mnejn jingħata |
|----------------------|--------------------------------------------------------------------------------------------------|-----------------------------|--------------------------------------------------------------------|--------------|--------------------------------------------|----------------|
| Ir-Renju Unit        | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                               | Irbesartan/idroklorotijazid | Irbesartan Hydrochlorothiazide<br>300 mg/25 mg Film-coated tablets | 300 mg/25 mg | Pillola miksija b'rita                     | Użu orali      |
| Ir-Renju Unit        | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                               | irbesartan                  | Irbesartan 75 mg Film-coated tablets                               | 75 mg        | Pillola miksija b'rita                     | Użu orali      |
| Ir-Renju Unit        | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                               | irbesartan                  | Irbesartan 150 mg Film-coated tablets                              | 150 mg       | Pillola miksija b'rita                     | Użu orali      |
| Ir-Renju Unit        | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                               | irbesartan                  | Irbesartan 300 mg Film-coated tablets                              | 300 mg       | Pillola miksija b'rita                     | Użu orali      |
| Ir-Renju Unit        | Waymade PLC<br>Sovereign House<br>Miles Grate Road, Basildon<br>Essex SS14 3FR<br>United Kingdom | Venlafaksina kloridrata     | Venlasov XL 75 mg Modified Release Capsules                        | 75 mg        | Kapsula li terhi l-medicina bil-mod, iebša | Użu orali      |
| Ir-Renju Unit        | Waymade PLC<br>Sovereign House<br>Miles Grate Road, Basildon<br>Essex SS14 3FR<br>United Kingdom | Venlafaksina kloridrata     | Venlasov XL 150 mg Modified Release Capsules                       | 150 mg       | Kapsula li terhi l-medicina bil-mod, iebša | Użu orali      |

| Stat Membru (fl-EEA) | Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq                                                      | INN          | Isem Ivvintat                         | Qawwa | Għamla farmaċewtika    | Mnejn jingħata |
|----------------------|-----------------------------------------------------------------------------------------------------------|--------------|---------------------------------------|-------|------------------------|----------------|
| Ir-Renju Unit        | Wockhardt UK Limited<br>Ash Road North<br>Wrexham Industrial Estate<br>Wrexham LL13 9UF<br>United Kingdom | Klopidogrel  | Clopidogrel 75 mg Film-coated Tablets | 75 mg | Pillola miksija b'rita | Użu orali      |
| Ir-Renju Unit        | YJBPort Limited<br>74 Briarwood Drive<br>Northwood Hills<br>Middlesex HA6 1PL<br>United Kingdom           | Idrokortizon | Hydrocortisone 10 mg Tablets          | 10 mg | Pillola                | Użu orali      |
| Ir-Renju Unit        | YJBPort Limited<br>74 Briarwood Drive<br>Northwood Hills<br>Middlesex HA6 1PL<br>United Kingdom           | Idrokortizon | Hydrocortisone 20 mg Tablets          | 20 mg | Pillola                | Użu orali      |





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