ISSN 1725-2423

Official Journal of the European Union

C 359

English edition

Information and Notices

Volume 53

31 December 2010

Notice No | Contents | Page

EN

Price: EUR 4

This issue closes the C series for 2010.

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 September 2010 to 31 October 2010

(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council [1]*)*

(2010/C 359/01)

[1] OJ L 136, 30.4.2004, p. 1.

— Issuing of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
1.9.2010	Brinavess	vernakalant hydrochloride	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/645/001-002	Concentrate for solution for infusion	C01BG11	6.9.2010
1.9.2010	Sycrest	Asenapine	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/10/640/001-006	Sublingual tablet	N05AH05	6.9.2010
6.9.2010	Rapiscan	regadenoson	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/10/643/001	Solution for injection	C01EB21	8.9.2010
17.9.2010	Ibandronic Acid Teva	Ibandronic acid	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/10/642/001-004	Film-coated tablet	M05BA06	21.9.2010
30.9.2010	Telmisartan Actavis	telmisartan	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland	EU/1/10/639/001-030	Tablet	C09CA07	5.10.2010
7.10.2010	Myclausen	mycophenolate mofetil	Herbert J. Passauer GmbH & Co. KG Stubenrauchstrasse 33, 14167 Berlin, Deutschland	EU/1/10/647/001-002	Film-coated tablet	L04AA06	11.10.2010
7.10.2010	Twynsta	telmisartan/amlodipine	Boehringer Ingelheim International GmbH Binger Strasse 173 - D - 55216 Ingelheim am Rhein, Deutschland	EU/1/10/648/001-028	Tablet	C09DB04	11.10.2010
28.10.2010	Clopidogrel HCS	Clopidogrel	HCS bvba H. Kennisstraat 53, B 2650 Edegem, België	EU/1/10/651/001-015	Film-coated tablet	B01AC04	2.11.2010

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
28.10.2010	Clopidogrel Teva Generics B.V.	Clopidogrel	Teva Generics B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/10/650/001-015	Film-coated tablet	B01AC04	4.11.2010
28.10.2010	Ruconest	Conestat alfa	Pharming Group N.V. Darwinweg 24, NL-2333 CR Leiden, Nederland	EU/1/10/641/001	Powder for solution for injection	Pending	4.11.2010

— **Issuing of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Rejected**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
16.9.2010	Zeftera	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België		20.9.2010

— **Modification of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
1.9.2010	Altargo	Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/390/001-004	8.9.2010
1.9.2010	Ecalta	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/416/001-002	6.9.2010
1.9.2010	Keppra	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef, 60, Brussel 1070, België	EU/1/00/146/001-032	6.9.2010
1.9.2010	Levitra	Bayer Schering Pharma AG 13342 Berlin, Deutschland	EU/1/03/248/001-015	6.9.2010
1.9.2010	Prevenar 13	Wyeth Lederle Vaccines S.A. Rue du Bosquet, 15 B-1348 Louvain-la-Neuve, Belgique	EU/1/09/590/001-006	6.9.2010
1.9.2010	Regranex	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/99/101/001	6.9.2010
1.9.2010	Relistor	Wyeth Europa Limited Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/08/463/001-003	6.9.2010
1.9.2010	Vfend	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/212/001-026	6.9.2010
1.9.2010	Zypadhera	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA, Houten, Nederland	EU/1/08/479/001-003	6.9.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
6.9.2010	Abraxane	Abraxis BioScience Limited Rosanne House, Parkway, Welwyn Garden City, Herts, AL8 6HG, United Kingdom	EU/1/07/428/001	9.9.2010
6.9.2010	Apidra	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/04/285/001-036	9.9.2010
6.9.2010	Cialis	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/02/237/001-009	9.9.2010
6.9.2010	Clopidogrel Winthrop	Sanofi-Aventis 174, avenue de France, F-75013 Paris, France	EU/1/08/465/001-020	9.9.2010
6.9.2010	Cymbalta	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/04/296/001-009	8.9.2010
6.9.2010	Dynastat	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/209/001-008	8.9.2010
6.9.2010	Emadine	Alcon Laboratories (UK) Ltd. Pentagon Park, Boundary Way, Hemel Hempstead, Herts HP2 7UD, United Kingdom	EU/1/98/095/001-004	9.9.2010
6.9.2010	Insuman	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/97/030/028-195	9.9.2010
6.9.2010	Menveo	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/614/001	9.9.2010
6.9.2010	M-M-RVAXPRO	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/337/001-013	9.9.2010
6.9.2010	Onglyza	Bristol Myers Squibb/AstraZeneca EEIG Bristol Myers Squibb House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, United Kingdom	EU/1/09/545/001-010	9.9.2010
6.9.2010	Oslif Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/09/586/001-010	9.9.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
6.9.2010	ProQuad	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/05/323/001-013	9.9.2010
6.9.2010	Relistor	Wyeth Europa Limited Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/08/463/001-011	8.9.2010
6.9.2010	Renvela	Genzyme Europe B.V. Gooimeer 10, 1411 DD Naarden, Nederland	EU/1/09/521/001-007	9.9.2010
6.9.2010	Thyrogen	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/99/122/001-002	9.9.2010
6.9.2010	Vimpat	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef, 60, Brussel 1070, België	EU/1/08/470/001-017	8.9.2010
6.9.2010	Viread	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/01/200/001-002	9.9.2010
6.9.2010	Xeristar	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/04/297/001-008	8.9.2010
6.9.2010	Xolair	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/05/319/001-010	8.9.2010
6.9.2010	Zerit	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/96/009/001-009	9.9.2010
6.9.2010	Zyprexa	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/96/022/002 EU/1/96/022/004 EU/1/96/022/006 EU/1/96/022/009-012 EU/1/96/022/014 EU/1/96/022/016-017 EU/1/96/022/019-034	8.9.2010
6.9.2010	Zyprexa Velotab	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/99/125/001-016	8.9.2010
10.9.2010	Pandemrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique	EU/1/08/452/001	14.9.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
10.9.2010	Siklos	ADDMEDICA 101, rue Saint Lazare, Paris 75009, FRANCE	EU/1/07/397/001	14.9.2010
16.9.2010	Alimta	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/04/290/001	20.9.2010
16.9.2010	Tracleer	Actelion Registration Ltd BSI Building 13th Floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/220/001-006	20.9.2010
17.9.2010	Xyrem	UCB Pharma Ltd. 208 Bath Road, Slough, Berkshire SL1 3WE, United Kingdom	EU/1/05/312/001	21.9.2010
23.9.2010	Kepivance	Biovitrum AB (publ) SE-112 76 Stockholm, Sverige	EU/1/05/314/001	27.9.2010
23.9.2010	Levemir	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/04/278/001-011	27.9.2010
23.9.2010	Revatio	Pfizer Limited Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/05/318/001-002	27.9.2010
27.9.2010	Caelyx	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/96/011/001-004	29.9.2010
27.9.2010	Panretin	Eisai Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom	EU/1/00/149/001	29.9.2010
30.9.2010	Clopidogrel Apotex	Apotex Europe B.V. Darwingweg 20, 2333 CR Leiden, Nederland	EU/1/09/568/001-018	5.10.2010
30.9.2010	Mepact	IDM PHARMA SAS 11-15 Quai De Dion Bouton, 92816 Puteaux Cedex, France	EU/1/08/502/001	6.10.2010
30.9.2010	Noxafil	SP Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/05/320/001	5.10.2010
30.9.2010	Rotarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique	EU/1/05/330/001-011	5.10.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
30.9.2010	Sprycel	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/06/363/001-015	5.10.2010
30.9.2010	Thalidomide Celgene	Celgene Europe Limited Riverside House, Riverside Walk, Windsor SL4 1NA, United Kingdom	EU/1/08/443/001	5.10.2010
5.10.2010	APTIVUS	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/05/315/001-002	7.10.2010
5.10.2010	Mircera	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/07/400/001-024	7.10.2010
5.10.2010	Revlimid	Celgene Europe Limited Riverside House, Riverside Walk, Windsor, Berkshire SL4 1NA, United Kingdom	EU/1/07/391/001-004	7.10.2010
7.10.2010	Cyanokit	Merck Santé s.a.s. 37, rue Saint-Romain, 69379 Lyon Cedex 08, France	EU/1/07/420/001-002	11.10.2010
7.10.2010	DuoTrav	Alcon Laboratories (UK) Ltd. Pentagon Park, Boundary Way, Hemel Hempstead, Herts HP2 7UD, United Kingdom	EU/1/06/338/001-003	11.10.2010
7.10.2010	Soliris	Alexion Europe S.A.S. 25, Boulevard de l'Amiral Bruix, 75016 Paris, France	EU/1/07/393/001	11.10.2010
11.10.2010	Retacrit	HOSPIRA Enterprises B.V. Randstad 22-11, 1316 BN, Almere, Nederland	EU/1/07/431/001-025	13.10.2010
14.10.2010	Alisade	Glaxo Group Ltd Greenford, Middlesex, UB6 ONN, United Kingdom	EU/1/08/474/001-003	19.10.2010
14.10.2010	Avamys	Glaxo Group Ltd Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/434/001-003	19.10.2010
14.10.2010	Biograstim	CT Arzneimittel GmbH Lengeder Straße 42a, D-13407 Berlin, Deutschland	EU/1/08/450/001-010	18.10.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
14.10.2010	Firmagon	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11, Copenhagen S 2300, Danmark	EU/1/08/504/001-003	18.10.2010
14.10.2010	Multaq	Sanofi-Aventis 174, avenue de France, F-75013 Paris, France	EU/1/09/591/001-004	18.10.2010
14.10.2010	Ratiograstim	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/08/444/001-012	18.10.2010
14.10.2010	Vidaza	Celgene Europe Ltd Riverside House, Riverside Walk, Windsor, SL4 1NA, United Kingdom	EU/1/08/488/001	18.10.2010
14.10.2010	Xarelto	Bayer Schering Pharma AG 13342 Berlin, Deutschland	EU/1/08/472/001-010	18.10.2010
15.10.2010	Riprazo	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/409/001-020	19.10.2010
15.10.2010	Silapo	STADA Arzneimittel AG Stadastrasse 2-18, 61118 Bad Vilbel, Deutschland	EU/1/07/432/001-022	19.10.2010
15.10.2010	Sprimeo	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/407/001-020	19.10.2010
25.10.2010	Axura	Merz Pharmaceuticals GmbH Eckenheimer Landstr. 100, D-60318 Frankfurt/Main - Deutschland	EU/1/02/218/001-003 EU/1/02/218/005-030	27.10.2010
25.10.2010	Azilect	Teva Pharma GmbH Kandelstrasse 10, Kirchzarten 79199, Deutschland	EU/1/04/304/001-007	29.10.2010
25.10.2010	Baraclude	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/06/343/001-007	27.10.2010
25.10.2010	Cerezyme	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/97/053/001-005	27.10.2010
25.10.2010	Champix	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/06/360/001-013	27.10.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
25.10.2010	Ebixa	H. Lundbeck A/S Ottiliavej 9, DK-2500 Valby, Danmark	EU/1/02/219/001-049	27.10.2010
25.10.2010	Epivir	ViiV Healthcare UK Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/96/015/001-005	27.10.2010
25.10.2010	Faslodex	AstraZeneca UK Limited Alderley Park, Macclesfield, Cheshire, SK10 4TG United Kingdom	EU/1/03/269/001-002	27.10.2010
25.10.2010	Forsteo	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/03/247/001-002	27.10.2010
25.10.2010	Herceptin	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/00/145/001	27.10.2010
25.10.2010	Irbesartan/Hydro-chlorothiazide Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/583/001-072	27.10.2010
25.10.2010	Karvea	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/97/049/001-039	27.10.2010
25.10.2010	Mabthera	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/98/067/001-002	27.10.2010
25.10.2010	Mirapexin	Boehringer Ingelheim International GmbH Binger Strasse 173- D - 55216 Ingelheim am Rhein, Deutschland	EU/1/97/051/001-006 EU/1/97/051/009-033	27.10.2010
25.10.2010	M-M-RVAXPRO	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/337/001-013	27.10.2010
25.10.2010	Pradaxa	Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/08/442/001-008	27.10.2010
25.10.2010	ProQuad	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/05/323/001-013	27.10.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
25.10.2010	Puregon	Organon N.V. Kloosterstraat 6, Postbus 20, 5340 BH Oss, Nederland	EU/1/96/008/001-041	27.10.2010
25.10.2010	Revlimid	Celgene Europe Limited Riverside House, Riverside Walk, Windsor, Berkshire SL4 1NA, United Kingdom	EU/1/07/391/001-004	27.10.2010
25.10.2010	Sifrol	Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/97/050/001-006 EU/1/97/050/009-033	27.10.2010
25.10.2010	Simponi	Centocor B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/09/546/001-004	27.10.2010
25.10.2010	Sprimeo	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/407/001-020	27.10.2010
25.10.2010	Sprycel	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/06/363/001-015	27.10.2010
25.10.2010	Toviaz	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/386/001-018	27.10.2010
25.10.2010	Vantavo	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/09/572/001-009	27.10.2010
25.10.2010	Vasovist	TMC Pharma Services Ltd. Finchampstead, Berks, RG40 4LJ, UK	EU/1/05/313/001-009	27.10.2010
25.10.2010	Vimpat	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef, 60, Brussel 1070, België	EU/1/08/470/001-017	27.10.2010
25.10.2010	Zonegran	Eisai Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom	EU/1/04/307/001-013	27.10.2010
25.10.2010	Zostavax	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/341/001-013	27.10.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
28.10.2010	Ambirix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique	EU/1/02/224/001-005	2.11.2010
28.10.2010	Aprovel	Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France - 75013 Paris, France	EU/1/97/046/001-039	2.11.2010
28.10.2010	Fertavid	SP Europe Rue de Stalle, 73 B-1180 Bruxelles, Belgique	EU/1/09/510/001-019	2.11.2010
28.10.2010	Hycamtin	SmithKline Beecham Ltd. 980 Great West Road, Brentford, Middlesex, TW8 9GS United Kingdom	EU/1/96/027/001 EU/1/96/027/003-007	4.11.2010
28.10.2010	Mimpara	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/04/292/001-012	4.11.2010
28.10.2010	NovoSeven	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/96/006/001-007	4.11.2010
28.10.2010	Olanzapine Neopharma	Neopharma Limited 57 High Street, Odiham, Hampshire RG29 1LF, United Kingdom	EU/1/07/426/001-011	1.11.2010
28.10.2010	Olanzapine Teva	Teva Pharma B.V. Computerweg 10, DR Utrecht 3542, Nederland	EU/1/07/427/001-057	1.11.2010
28.10.2010	PegIntron	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/00/131/001-050	4.11.2010
28.10.2010	Travatan	Alcon Laboratories (UK) Ltd. Boundary Way, Hemel Hempstead, Herts HP2 7UD, United Kingdom	EU/1/01/199/001-002	4.11.2010
28.10.2010	ViraferonPeg	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/00/132/001-050	4.11.2010
29.10.2010	Mycamine	Astellas Pharma Europe B.V. Elisabethhof 19, 2353 EW Leiderdorp, Nederland	EU/1/08/448/001-002	5.11.2010

— **Withdrawal of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
6.9.2010	ImmunoGam	Cangene Europe Limited Parkshot House, 5 Kew Road, Richmond, Surrey TW9 2PR, United Kingdom	EU/1/10/613/001-002	9.9.2010
27.9.2010	Enviage	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/406/001-020	29.9.2010
28.10.2010	NeoSpect	CIS bio international Boite Postale 32 - F-91192 Gif-sur-Yvette – France	EU/1/00/154/001-002	5.11.2010

— **Suspension of a marketing authorization (Article 20 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
16.9.2010	Clopidogrel 1A Pharma	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/542/001-007	20.9.2010
16.9.2010	Clopidogrel Acino	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/532/001-007	20.9.2010
16.9.2010	Clopidogrel Acino Pharma	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/549/001-007	20.9.2010
16.9.2010	Clopidogrel Acino Pharma GmbH	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/548/001-007	20.9.2010
16.9.2010	Clopidogrel Hexal	Acino Pharma GmbH Am Windfeld 35, Miesbach 83714, Deutschland	EU/1/09/534/001-007	20.9.2010
16.9.2010	Clopidogrel ratiopharm	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/554/001-008	20.9.2010
16.9.2010	Clopidogrel ratiopharm GmbH	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/541/001-008	20.9.2010
16.9.2010	Clopidogrel Sandoz	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/547/001-007	20.9.2010

— **Issuing of a marketing authorization (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council [1]): Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
6.9.2010	Bovilis BTV8	Inactivated Bluetongue virus	Intervet International B.V. Wim de Körverstraat 35, NL - 5831 Boxmeer, Nederland	EU/2/10/106/001-014	Suspension for injection	QI02AA08(cattle) QI04AA02(sheep)	8.9.2010
16.9.2010	Rhiniseng	inactivated vaccine against atrophic rhinitis in pigs	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170- Amer (Girona), España	EU/2/10/109/001-009	Suspension for injection	QI09AB04	21.9.2010
30.9.2010	Coxevac	Inactivated Coxiella burnetii vaccine	CEVA SANTE ANIMALE 10 avenue de la Ballastière, 33500 Libourne, France	EU/2/10/110/001-002	Suspension for injection	QI03AB ngi	5.10.2010

[1] OJ L 136, 30.4.2004, p. 1.

— **Modification of a marketing authorization (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
1.9.2010	Acticam	Ecuphar NV Legeweg 157-I, B-8020 Oostkamp, België	EU/2/08/088/001-004	6.9.2010
17.9.2010	Porcilis AR-T DF	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/00/026/001-004	21.9.2010
23.9.2010	Porcilis AR-T DF	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/00/026/001-006	27.9.2010
30.9.2010	Poulvac FluFend H5N3 RG	Fort Dodge Animal Health Ltd Flanders Road, Hedge End, Southampton SO30 4QH, United Kingdom	EU/2/06/060/001-002	13.10.2010
30.9.2010	Prac-Tic	Novartis Sanidad Animal S.L. Calle de la Marina, 206, E - Barcelona 08013, ESPANA	EU/2/06/066/001-012	5.10.2010
5.10.2010	Nobilis Influenza H5N2	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/06/061/001-004	7.10.2010
11.10.2010	Equioxx	MERIAL 29 avenue Tony Garnier, 69007 LYON, France	EU/2/08/083/001-005	13.10.2010
14.10.2010	Cerenia	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/2/06/062/005	18.10.2010
14.10.2010	Improvac	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/09/095/001-006	18.10.2010
14.10.2010	Novem	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/04/042/001-002 EU/2/04/042/007-010	18.10.2010
14.10.2010	Posatex	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/08/081/001-003	18.10.2010
14.10.2010	Quadrisol	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/97/005/001 EU/2/97/005/005	18.10.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
28.10.2010	Trocoxil	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ United Kingdom	EU/2/08/084/001-005	4.11.2010
28.10.2010	Zactran	MERIAL 29 avenue Tony Garnier, 69007 LYON, France	EU/2/08/082/001-006	4.11.2010

— **Suspension of a marketing authorization (Article 45 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
27.9.2010	Flexicam	Dechra Veterinary Products A/S Mekuvej 9, 7171 Uldum, Danmark	EU/2/06/058/001-003	29.9.2010

— **Lift of suspension of a marketing authorization (Article 45 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
1.9.2010	Porcilis Pesti	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/99/016/001-006	6.9.2010

Anyone wishing to consult the public assessment report on the medicinal products in question and the decisions relating thereto is invited to contact:

The European Medicines Agency
7, Westferry Circus,
Canary Wharf
UK - LONDON E14 4H

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 July 2010 to 31 August 2010

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC [1] or Article 38 of Directive 2001/82/EC [2])

(2010/C 359/02)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
31.8.2010	PecFent	Archimedes Development Ltd, Nottingham, NGT7 2TN, United Kingdom	These Decisions are addressed to the Member States	3.9.2010

— Refusal of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
6.8.2010	Myderison	See Annex I	See Annex I	10.8.2010

— Suspension of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
10.8.2010	Pregsure BVD and associated names	See Annex II	See Annex II	11.8.2010

— Revocation of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
6.8.2010	Myderison	See Annex I	See Annex I	10.8.2010

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 311, 28.11.2001, p. 1.

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 September 2010 to 31 October 2010

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC [1] or Article 38 of Directive 2001/82/EC [2])

(2010/C 359/03)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
15.10.2010	Xalatan and associated names	See Annex III	See Annex III	18.10.2010
5.10.2010	Norsed Combi D and associated names	See Annex IV	See Annex IV	6.10.2010
16.9.2010	Atacand Plus and associated names	See Annex V	See Annex V	20.9.2010
30.9.2010	Daivobet	See Annex VI	See Annex VI	4.10.2010
5.10.2010	Fortipan Combi D and associated names	See Annex VII	See Annex VII	6.10.2010
1.9.2010	Brinavess	Merck Sharp & Dohme Limited, Hertford Road, Hodderson, Hertfordshire EN11 9BU, United Kingdom	These Decisions are addressed to the Member States	3.9.2010
28.10.2010	Ruconest	Pharming Group N.V., Darwinweg 24, NL-2333 CR Leiden, Nederland	These Decisions are addressed to the Member States	4.11.2010

— Refusal of modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
1.9.2010	Genotropin	See Annex VIII	See Annex VIII	2.9.2010

— Suspension of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
7.10.2010	Pregsure BVD and associated names	See Annex IX	See Annex IX	8.10.2010
4.10.2010	Octagam	See Annex X	See Annex X	5.10.2010

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 311, 28.11.2001, p. 1.

ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCT, ROUTE OF ADMINISTRATION, APPLICANTS/MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Czech Republic		Meditop Pharmaceutical Co. Ltd. Ady Endre u. 1. Pilisborosjenő 2097 Hungary	Myderison	50 mg 150 mg	film-coated tablet	oral use
Germany		Meditop Pharmaceutical Co. Ltd. Ady Endre u. 1. Pilisborosjenő 2097 Hungary	Myderison	50 mg 150 mg	film-coated tablet	oral use
Hungary	Meditop Pharmaceutical Co. Ltd. Ady Endre u. 1. Pilisborosjenő 2097 Hungary		Myderison	50 mg 150 mg	film-coated tablet	oral use
Lithuania		Meditop Pharmaceutical Co. Ltd. Ady Endre u. 1. Pilisborosjenő 2097 Hungary	Myderison	50 mg 150 mg	film-coated tablet	oral use
Poland		Meditop Pharmaceutical Co. Ltd. Ady Endre u. 1. Pilisborosjenő 2097 Hungary	Myderison	50 mg 150 mg	film-coated tablet	oral use
Romania		Meditop Pharmaceutical Co. Ltd. Ady Endre u. 1. Pilisborosjenő 2097 Hungary	Myderison	50 mg 150 mg	film-coated tablet	oral use
Slovak Republic		Meditop Pharmaceutical Co. Ltd. Ady Endre u. 1. Pilisborosjenő 2097 Hungary	Myderison	50 mg 150 mg	film-coated tablet	oral use

ANNEX II

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE VETERINARY MEDICINAL PRODUCT, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	Product name	Pharmaceutical form	Strength	Target animal species	Route of administration
Belgium	Pfizer Animal Health Rue Laid Burniat 1 1348 - Louvain-la-Neuve BELGIUM	PREGSURE BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Bulgaria	Pfizer Animal Health MA EEIG Ramsgate Road Sandwich, Kent CT13 9NJ UNITED KINGDOM	PregSure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Czech Republic	Pfizer, spol. s r.o. Stroupežnického 17 150 00 Praha CZECH REPUBLIC	PregSure BVD injekční emulze	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Estonia	Pfizer Animal Health Rue Laid Burniat 1 1348 - Louvain-la-Neuve BELGIUM	PregSure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
France	PFIZER 23/25 Avenue du Docteur Lannelongue 75014 Paris FRANCE	PREGSURE BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Germany	Pfizer GmbH Linkstraße 10 D-10785 Berlin GERMANY	PregSure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Greece	PFIZER HELLAS S.A 243 Messogeion Ave. Neo Psychiko GR-154 51 GREECE	PREGSURE BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous

Member State	Marketing Authorisation Holder	Product name	Pharmaceutical form	Strength	Target animal species	Route of administration
Hungary	Pfizer Kft. Alkotas u 53 MOM Park 'F' Épület Budapest H-1123 HUNGARY	PregSure BVD vakcina A.U.V.	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Ireland	Pfizer Healthcare Ireland trading as Pfizer Animal Health Ringaskiddy County Cork IRELAND	PregSure BVD Emulsion for Injection	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Italy	Pfizer Italia Srl Via Isonzo 71 04100 – Latina ITALY	Pregsure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Lithuania	Pfizer Animal Health S.A. Rue Laid Burniat 1 B-1348 - Louvain-la-Neuve BELGIUM	PREGSURE BVD, injekcinė emulsija	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Latvia	Pfizer Ltd Ramsgate Road Sandwich, Kent CT13 9NJ UNITED KINGDOM	PregSure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Poland	Pfizer Trading Polska Sp. z o.o. ul. Rzymowskiego 34 02-697 Warszawa POLAND	PregSure BVD emulsja do wstrzykiwań	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Portugal	Laboratórios Pfizer Lda Lagoas Park – Edifício 10 2740-244 Porto Salvo PORTUGAL	Pregsure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Romania	Pfizer Animal Health MA EEIG Ramsgate Road, Sandwich, Kent CT 13 9NJ UNITED KINGDOM	Pregsure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous

Member State	Marketing Authorisation Holder	Product name	Pharmaceutical form	Strength	Target animal species	Route of administration
Slovenia	Pfizer Luxembourg SARL Gran Duchy of Luxembourg 51, Avenue J.F. Kennedy L-1855 - Luxembourg	Pregsure BVD emulzija za injiciranje	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Slovak republic	Pfizer Luxembourg SARL o.z. Pfizer AH Pribinova 25 81109 Bratislava SLOVAK REPUBLIC	Pregsure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Spain	Pfizer SA Avda. De Europa, 20 B Parque Empresarial la Moraleja (Alcobendas) 28108 SPAIN	PREGSURE BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
The Netherlands	Pfizer Animal Health BV Rivium Westlaan 142 2909 LD Capelle a/d Ijssel P.O. Box 37 2900 AA Capelle a/d Ijssel THE NETHERLANDS	PREGSURE BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
United Kingdom	Pfizer Ltd Ramsgate Road Sandwich, Kent CT13 9NJ UNITED KINGDOM	Pregsure BVD Emulsion for Injection	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous

ANNEX III

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCT, ROUTES OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration	Content
Austria	Pfizer Corporation Austria Ges.m.b.H. Floridsdorfer Hauptstrasse 1 A - 1210 Wien, Austria	Xalatan	0,005 % w/v	Eye drops, solution	Ocular use	2,5 ml
Belgium	Pfizer SA Boulevard de la Plaine 17 B-1050 Brussels, Belgium	Xalatan	0,005 %	Eye drops, solution	Ocular use	2,5 ml
Bulgaria	Pfizer Enterprises SARL, Rond-point du Kirchberg, 51, Avenue J.F. Kennedy, L-1855 Luxembourg, G. D. of Luxembourg	Xalatan	50 micrograms/ ml	Eye drops, solution	Topical use	2,5 ml
Czech Republic	Pfizer. s r.o., Stroupežnického 17, 150 00 Prague 5, Czech Republic	Xalatan	0,005 % w/v	Eye drops, solution	Topical use	2,5 ml
Denmark	Pfizer ApS, Lautrupvang 8, 2750 Ballerup, Denmark	Xalatan	50 microg/ ml	Eye drops, solution	Topical use	2,5 ml
Estonia	Pfizer Enterprises SARL 51, Avenue J.F. Kennedy Rond-Point du Kirchberg L-1855 Luxembourg	Xalatan	50 micrograms / ml	Eye drops, solution	Ocular use	2,5 ml
Finland	Pfizer Oy, Tietokuja 4, 00330 Helsinki, Finland	Xalatan	50 microg/ml	Eye drops, solution	Topical use	2,5 ml
France	Pfizer Holding France 23-25 Avenue du Docteur Lannelongue 75014 Paris France	Xalatan	0,005 % w/v	Eye drops, solution	Topical use	2,5 ml
Germany	Pharmacia GmbH Linkstraße 10 10785 Berlin, Germany	Xalatan	0,005 % w/v	Eye drops, solution	Ocular use	2,5 ml

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration	Content
Germany	Pharmacia GmbH, Linkstraße 10 10785 Berlin, Germany	Latanoprost Pharmacia & Upjohn	0,005 % w/v	Eye drops, solution	Ocular use	2,5 ml
Greece	Pfizer Hellas A. E. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Xalatan	50 mcg/ ml	Eye drops, solution	Topical use	2,5 ml
Hungary	Pfizer KFT, 1123 Budapest, Alkotás u. 53. MOM Park 'F' Ép., Hungary	Xalatan	0,05 mg/ml	Eye drops, solution	Topical use	2,5 ml
Iceland	Pfizer ApS, Lautrupvang 8, 2750 Ballerup, Denmark	Xalatan	50 microg/ ml	Eye drops, solution	Topical use	2,5 ml
Ireland	Pharmacia Ireland Limited 9 Riverwalk National Digital Park Citywest Business Campus Dublin 24 Ireland	Xalatan	0,005 % w/v	Eye drops, solution	Topical use	2,5 ml
Italy	Pfizer Italia S.r.l. Via Isonzo, 71 04100 Latina - Italy	Xalatan	0,005	Eye drops, solution	Topical use	2,5 ml
Latvia	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Xalatan	0,005 % w/v	Eye drops, solution	Topical use	2,5 ml
Lithuania	Pfizer Europe MA EEIG Ramsgate Road Sandwich, Kent CT13 9NJ United Kingdom	Xalatan	0,005 % w/v	Eye drops, solution	Ocular use	2,5 ml
Luxembourg	Pfizer SA Boulevard de la Plaine 17 B-1050 Brussels, Belgium	Xalatan	0,005 %	Eye drops, solution	Ocular use	2,5 ml

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration	Content
Malta	Pfizer Hellas S.A. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Xalatan	0,005 % w/v	Eye drops, solution	Topical use	2,5 ml
Netherlands	Pfizer bv Rivium Westlaan 142 2909 LD Capelle a/d IJssel The Netherlands	Xalatan	50 microgram/ml	Eye drops, solution	Topical use	2,5 ml
Norway	Pfizer AS Pb. 3 1324 Lysaker Norway	Xalatan	0,005 % w/v	Eye drops, solution	Topical use	2,5 ml
Poland	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Xalatan	0,005 % w/v	Eye drops, solution	Ocular use	2,5 ml
Portugal	Laboratorios Pfizer, Lda., Lagoas Park, Edifício 10, 2740-271 Porto Salvo, Portugal	Xalatan	0,005 % w/v	Eye drops, solution	Topical use	2,5 ml
Romania	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Xalatan	0,005 % w/v	Eye drops, solution	Ocular use	2,5 ml
Slovak Republic	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Xalatan	0,005 % w/v	Eye drops, solution	Topical use	2,5 ml
Slovenia	Pfizer Luxembourg SARL, 51, Avenue J. F. Kennedy, L-1855 Luxembourg, Luxembourg	Xalatan 50 mikrogramov/ml kapljice za oko, raztopina	0,005 % w/v	Eye drops, solution	Topical use	2,5 ml

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration	Content
Spain	Pfizer, S.A. Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Xalatan	0,005 % w/v	Eye drops, solution	Ocular use	2,5 ml
Sweden	Pfizer AB Vetenskapsvagen 10, SE 191 90 Sollentuna Sweden	Xalatan	0,005 % w/v	Eye drops, solution	Topical use	2,5 ml
United Kingdom	Pfizer Limited Ramsgate Road Sandwich, Kent CT13 9NJ United Kingdom	Xalatan	0,005 % w/v	Eye drops, solution	Topical use	2,5 ml

ANNEX IV

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANTS AND MARKETING AUTHORISATION HOLDER IN THE MEMBER STATES

Member State EU/EEA	Marketing authorisation holder	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Bulgaria		Sanofi-Aventis Bulgaria EOOD 103, blvd Alexander Stamboliiski 1303 Sofia Bulgaria	Actonel Combi D	35 mg + 1 000 mg/880 IU	film-coated tablets + effervescent granules	Oral use
France		Procter & Gamble Pharmaceuticals France 163-165 Quai Aulagnier 92600 Asnières-sur-Seine France	Norsedcombi	35 mg + 1 000 mg/880 IU	film-coated tablets + effervescent granules	Oral use
Germany		Warner Chilcott Deutschland GmbH Dr.-Otto-Röhm-Strasse 2-4 64331 Weiterstadt Germany	Norsed plus Calcium D	35 mg + 1 000 mg/880 IU	film-coated tablets + effervescent granules	Oral use
Ireland		Warner Chilcott UK Limited, Old Belfast Road, Millbrook, Larne, County Antrim, BT40 2SH United Kingdom	Optinate Plus Ca &D	35 mg + 1 000 mg/880 IU	film-coated tablets + effervescent granules	Oral use
Italy		sanofi-aventis S.p.A. viale Luigi Bodio, 37/B 20158 Milan Italy	Opticalcio D3	35 mg + 1 000 mg/880 IU	film-coated tablets + effervescent granules	Oral use
Sweden	sanofi-aventis S.p.A. Viale Luigi Bodio, 37/b 20158 Milano Italy		Norsed Combi D	35 mg + 1 000 mg/880 IU	film-coated tablets + effervescent granules	Oral use

ANNEX V

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Austria	AstraZeneca Österreich GmbH., Schwarzenbergplatz 7, A-1037 Wien, Austria	Atacand plus mite 8 mg/12,5 mg Tabletten	8 mg/12,5 mg	Tablet	Oral use
Austria	AstraZeneca Österreich GmbH., Schwarzenbergplatz 7, A-1037 Wien, Austria	Atacand plus 16 mg/12,5 mg Tabletten	16 mg/12,5 mg	Tablet	Oral use
Austria	AstraZeneca Österreich GmbH., Schwarzenbergplatz 7, A-1037 Wien, Austria	Atacand Plus 32 mg/12,5 mg Tabletten	32 mg/12,5 mg	Tablet	Oral use
Austria	AstraZeneca Österreich GmbH., Schwarzenbergplatz 7, A-1037 Wien, Austria	Atacand Plus 32 mg/25 mg Tabletten	32 mg/25 mg	Tablet	Oral use
Austria	Takeda Pharma Ges.m.b.H., Seidengasse 33-35, 1070 Wien, Austria	Blopress Plus 8 mg/12,5 mg - Tabletten	8 mg/12,5 mg	Tablet	Oral use
Austria	Takeda Pharma Ges.m.b.H., Seidengasse 33-35, 1070 Wien, Austria	Blopress Plus 16 mg/12,5 mg - Tabletten	16 mg/12,5 mg	Tablet	Oral use
Austria	Takeda Pharma Ges.m.b.H., Seidengasse 33-35, 1070 Wien, Austria	Blopress Plus 32 mg/ 12,5 mg - Tabletten	32 mg/12,5 mg	Tablet	Oral use
Austria	Takeda Pharma Ges.m.b.H., Seidengasse 33-35, 1070 Wien, Austria	Blopress Plus 32 mg/ 25 mg - Tabletten	32 mg/25 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels Belgium	Atacand Plus	8 mg/12,5 mg	Tablet	Oral use
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels Belgium	Atacand Plus	16 mg/12,5 mg	Tablet	Oral use
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels Belgium	Atacand Plus	32 mg/12,5 mg	Tablet	Oral use
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels Belgium	Atacand Plus	32 mg/25 mg	Tablet	Oral use
Cyprus	AstraZeneca AB, S-151 85 Södertälje, Sweden	Atacand Plus	16 mg/12,5 mg	Tablet	Oral use
Czech Republic	AstraZeneca UK Ltd., Macclesfield, Cheshire, United Kingdom	Atacand Plus 16 + 12,5 mg	16 mg/12,5 mg	Tablet	Oral use
Denmark	AstraZeneca A/S Roskildevej 22 DK-2620 Albertslund, Denmark	Atacand Zid 8 mg/12,5 mg	8 mg/12,5 mg	Tablet	Oral use
Denmark	AstraZeneca A/S Roskildevej 22 DK-2620 Albertslund, Denmark	Atacand Zid 16 mg/12,5 mg	16 mg/12,5 mg	Tablet	Oral use
Denmark	AstraZeneca A/S Roskildevej 22 DK-2620 Albertslund, Denmark	Atacand Zid 32 mg/12,5 mg	32 mg/12,5 mg	Tablet	Oral use
Denmark	AstraZeneca A/S Roskildevej 22 DK-2620 Albertslund, Denmark	Atacand Zid 32 mg/25 mg	32 mg/25 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Estonia	AstraZeneca AB, Strängnäsvägen 44, S-151 85 Södertälje, Sweden	ATACAND PLUS	16 mg/12,5 mg	Tablet	Oral use
Estonia	AstraZeneca AB, Strängnäsvägen 44, S-151 85 Södertälje, Sweden	ATACAND PLUS	32 mg/12,5 mg	Tablet	Oral use
Estonia	AstraZeneca AB, Strängnäsvägen 44, S-151 85 Södertälje, Sweden	ATACAND PLUS	32 mg/25 mg	Tablet	Oral use
Finland	AstraZeneca Oy Luomanportti 3 FI-02200 Espoo Finland	Atacand Plus	8 mg/12,5 mg	Tablet	Oral use
Finland	AstraZeneca Oy Luomanportti 3 FI-02200 Espoo Finland	Atacand Plus	16 mg/12,5 mg	Tablet	Oral use
Finland	AstraZeneca Oy Luomanportti 3 FI-02200 Espoo Finland	Atacand Plus	32 mg/12,5 mg	Tablet	Oral use
Finland	AstraZeneca Oy Luomanportti 3 FI-02200 Espoo Finland	Atacand Plus	32 mg/25 mg	Tablet	Oral use
France	AstraZeneca 1, Place Renault 92844 Rueil-Malmaison Cedex France	Hytacand 8 mg/12,5 mg comprimé	8 mg/12,5 mg	Tablet	Oral use
France	AstraZeneca 1, Place Renault 92844 Rueil-Malmaison Cedex France	Hytacand 16 mg/12,5 mg comprimé	16 mg/12,5 mg	Tablet	Oral use
France	Laboratoires Takeda, 11-15, quai de Dion Bouton, 92816 Puteaux Cedex, France	CoKenzen 8 mg/12,5 mg comprimé	8 mg/12,5 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
France	Laboratoires Takeda, 11-15, quai de Dion Bouton, 92816 Puteaux Cedex, France	CoKenzen 16 mg/12,5 mg comprimé	16 mg/12,5 mg	Tablet	Oral use
Germany	AstraZeneca GmbH 22876 Wedel, Germany	Atacand Plus 8/12,5 mg	8 mg/12,5 mg	Tablet	Oral use
Germany	AstraZeneca GmbH 22876 Wedel, Germany	Atacand Plus 16/12,5 mg	16 mg/12,5 mg	Tablet	Oral use
Germany	AstraZeneca GmbH 22876 Wedel, Germany	Atacand Plus 32/12,5 mg Tabletten	32 mg/12,5 mg	Tablet	Oral use
Germany	AstraZeneca GmbH 22876 Wedel, Germany	Atacand Plus forte 32/25 mg Tabletten	32 mg/25 mg	Tablet	Oral use
Germany	Takeda Pharma GmbH, Viktoriaallee 3-5, 52066 Aachen, Germany	Blopress 8 mg Plus 12,5 mg Tabletten.	8 mg/12,5 mg	Tablet	Oral use
Germany	Takeda Pharma GmbH, Viktoriaallee 3-5, 52066 Aachen, Germany	Blopress 16 mg Plus 12,5 mg Tabletten	16 mg/12,5 mg	Tablet	Oral use
Germany	Takeda Pharma GmbH, Viktoriaallee 3-5, 52066 Aachen, Germany	Blopress 32 mg Plus 12,5 mg Tabletten	32 mg/12,5 mg	Tablet	Oral use
Germany	Takeda Pharma GmbH, Viktoriaallee 3-5, 52066 Aachen, Germany	Blopress forte 32 mg Plus 25 mg Tabletten	32 mg/25 mg	Tablet	Oral use
Greece	AstraZeneca SA Theotokopoulou 4 & Astronafton 151 25 Maroussi Greece	Atacand Plus	8 mg/12,5 mg	Tablet	Oral use
Greece	AstraZeneca SA Theotokopoulou 4 & Astronafton 151 25 Maroussi Greece	Atacand Plus	16 mg/12,5 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Greece	AstraZeneca SA Theotokopoulou 4 & Astronafton 151 25 Maroussi Greece	Atacand Plus	32 mg/12,5 mg	Tablet	Oral use
Greece	AstraZeneca SA Theotokopoulou 4 & Astronafton 151 25 Maroussi Greece	Atacand Plus	32 mg/25 mg	Tablet	Oral use
Hungary	AstraZeneca Kft. 1113 Budapest, Bocskai út 134-146 Hungary	Atacand Plus	16 mg/12,5 mg	Tablet	Oral use
Iceland	AstraZeneca A/S Roskildevej 22, DK-2620 Albertslund, Denmark	Atacand Plus	16 mg/12,5 mg	Tablet	Oral use
Iceland	AstraZeneca A/S Roskildevej 22, DK-2620 Albertslund, Denmark	Atacand Plus	32 mg/12,5 mg	Tablet	Oral use
Iceland	AstraZeneca A/S Roskildevej 22, DK-2620 Albertslund, Denmark	Atacand Plus	32 mg/25 mg	Tablet	Oral use
Ireland	AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, United Kingdom	Atacand Plus 8/12,5 mg	8 mg/12,5 mg	Tablet	Oral use
Ireland	AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, United Kingdom	Atacand Plus 16/12,5 mg	16 mg/12,5 mg	Tablet	Oral use
Ireland	Takeda UK Limited, Takeda House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire HP10 OHH United Kingdom.	Blopress Plus 8 mg/12,5 mg tablets	8 mg/12,5 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Ireland	Takeda UK Limited, Takeda House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire HP10 OHH United Kingdom.	Blopress Plus 16 mg/12,5 mg tablets	16 mg/12,5 mg	Tablet	Oral use
Ireland	Takeda UK Limited, Takeda House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire HP10 OHH United Kingdom.	Blopress Plus 32 mg/12,5 mg tablets	32 mg/12,5 mg	Tablet	Oral use
Ireland	Takeda UK Limited, Takeda House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire HP10 OHH United Kingdom.	Blopress Plus 32 mg/25 mg tablets	32 mg/25 mg	Tablet	Oral use
Italy	AstraZeneca SpA Palazzo Volta-via F Sforza – 20080 Basiglio (MI) – Italy	Ratacand Plus	8 mg/12,5 mg	Tablet	Oral use
Italy	AstraZeneca SpA Palazzo Volta-via F Sforza – 20080 Basiglio (MI) – Italy	Ratacand Plus	16 mg/12,5 mg	Tablet	Oral use
Italy	AstraZeneca SpA Palazzo Volta-via F Sforza – 20080 Basiglio (MI) – Italy	Ratacand Plus	32 mg/12,5 mg	Tablet	Oral use
Italy	AstraZeneca SpA Palazzo Volta-via F Sforza – 20080 Basiglio (MI) – Italy	Ratacand Plus	32 mg/25 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Italy	Takeda Italia Farmaceutici S.p.A., Via Elio Vittorini, 129 00144 Roma Italy	Blopresid 8/12,5 mg compresse	8 mg/12,5 mg	Tablet	Oral use
Italy	Takeda Italia Farmaceutici S.p.A., Via Elio Vittorini, 129 00144 Roma Italy	Blopresid 16/12,5 mg compresse	16 mg/12,5 mg	Tablet	Oral use
Italy	Takeda Italia Farmaceutici S.p.A., Via Elio Vittorini, 129 00144 Roma Italy	Blopresid 32 mg/12,5 mg compresse	32 mg/12,5 mg	Tablet	Oral use
Italy	Takeda Italia Farmaceutici S.p.A., Via Elio Vittorini, 129 00144 Roma Italy	Blopresid 32 mg/25 mg compresse	32 mg/25 mg	Tablet	Oral use
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels Belgium	Atacand Plus	8 mg/12,5 mg	Tablet	Oral use
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels Belgium	Atacand Plus	16 mg/12,5 mg	Tablet	Oral use
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels Belgium	Atacand Plus	32 mg/12,5 mg	Tablet	Oral use
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels Belgium	Atacand Plus	32 mg/25 mg	Tablet	Oral use
Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Atacand Plus 8/12,5	8 mg/12,5 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Atacand Plus 16/12,5	16 mg/12,5 mg	Tablet	Oral use
Norway	AstraZeneca AS Boks 200 Vinderen NO-0319 Oslo, Norway	Atacand Plus Mite	8 mg/12,5 mg	Tablet	Oral use
Norway	AstraZeneca AS Boks 200 Vinderen NO-0319 Oslo, Norway	Atacand Plus	16 mg/12,5 mg	Tablet	Oral use
Norway	AstraZeneca AS Boks 200 Vinderen NO-0319 Oslo, Norway	Atacand Plus	32 mg/12,5 mg	Tablet	Oral use
Norway	AstraZeneca AS Boks 200 Vinderen NO-0319 Oslo, Norway	Atacand Plus	32 mg/25 mg	Tablet	Oral use
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, 7, Queluz de Baixo 2730-097 Barcarena, Portugal	Hytacand	8 mg/12,5 mg	Tablet	Oral use
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, 7, Queluz de Baixo 2730-097 Barcarena, Portugal	Hytacand 16 mg	16 mg/12,5 mg	Tablet	Oral use
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, 7, Queluz de Baixo 2730-097 Barcarena, Portugal	Hytacand	32 mg/12,5 mg	Tablet	Oral use
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, 7, Queluz de Baixo 2730-097 Barcarena, Portugal	Hytacand	32 mg/25 mg	Tablet	Oral use
Portugal	Lusomedicamenta - Sociedade Técnica Farmacêutica, S.A., Estrada Consiglieri Pedroso, 69 B - Queluz de Baixo 2730-055 Barcarena, Portugal	Blopress	8 mg/12,5 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Portugal	Lusomedicamenta - Sociedade Técnica Farmacêutica, S.A., Estrada Consiglieri Pedroso, 69 B - Queluz de Baixo 2730-055 Barcarena, Portugal	Blopress	16 mg/12,5 mg	Tablet	Oral use
Portugal	Lusomedicamenta - Sociedade Técnica Farmacêutica, S.A. Estrada Consiglieri Pedroso, 69 B - Queluz de Baixo 2730-055 Barcarena, Portugal	Blopress	32 mg/12,5 mg	Tablet	Oral use
Portugal	Lusomedicamenta - Sociedade Técnica Farmacêutica, S.A., Estrada Consiglieri Pedroso, 69 B - Queluz de Baixo 2730-055 Barcarena, Portugal	Blopress	32 mg/25 mg	Tablet	Oral use
Slovak Republic	AstraZeneca AB, S-151 85 Södertälje, Sweden	Atacand Plus 16/12,5 mg	16 mg/12,5 mg	Tablet	Oral use
Slovak Republic	AstraZeneca AB, S-151 85 Södertälje, Sweden	Atacand Plus	32 mg/12,5 mg	Tablet	Oral use
Slovak Republic	AstraZeneca AB, S-151 85 Södertälje, Sweden	Atacand Plus	32 mg/25 mg	Tablet	Oral use
Slovenia	AstraZeneca UK Limited 15 Stanhope Gate London W1K 1LN United Kingdom	Atacand Plus 16/12,5 mg	16 mg/12,5 mg	Tablet	Oral use
Spain	AstraZeneca Farmacéutica Spain, S.A. Parque Norte.Edificio Roble. C/ Serrano Galvache 56 28033 Madrid, Spain	Atacand Plus 16 mg/12,5 mg	16 mg/12,5 mg	Tablet	Oral use
Spain	AstraZeneca Farmacéutica Spain, S.A. Parque Norte.Edificio Roble. C/ Serrano Galvache 56 28033 Madrid, Spain	Atacand Plus 32 mg/12,5 mg	32 mg/12,5 mg	Tablet	Oral use
Spain	AstraZeneca Farmacéutica Spain, S.A. Parque Norte.Edificio Roble. C/ Serrano Galvache 56 28033 Madrid, Spain	Atacand Plus Forte 32 mg/25 mg	32 mg/25 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Spain	Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, London, WC2B 4AE, United Kingdom	Blopress Plus 8/12,5 mg comprimidos	8 mg/12,5 mg	Tablet	Oral use
Spain	Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, London, WC2B 4AE, United Kingdom	Blopress Plus 16/12,5 mg comprimidos	16 mg/12,5 mg	Tablet	Oral use
Spain	Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, London, WC2B 4AE, United Kingdom	Blopress Plus 32 mg/12,5 mg comprimidos	32 mg/12,5 mg	Tablet	Oral use
Spain	Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, London, WC2B 4AE, United Kingdom	Blopress Forte 32 mg/25 mg comprimidos	32 mg/25 mg	Tablet	Oral use
Spain	Almirall S.A., Ronda General Mitre, 151 08022 Barcelona, Spain	Parapres Plus 16 mg/12,5 mg comprimidos	16 mg/12,5 mg	Tablet	Oral use
Spain	Almirall S.A., Ronda General Mitre, 151 08022 Barcelona, Spain	Parapres Plus 32 mg/12,5 mg comprimidos	32 mg/12,5 mg	Tablet	Oral use
Spain	Almirall S.A., Ronda General Mitre, 151 08022 Barcelona, Spain	Parapres Plus Forte 32 mg/25 mg comprimidos	32 mg/25 mg	Tablet	Oral use
Sweden	AstraZeneca AB 151 85 Södertälje, Sweden	Atacand Plus	8 mg/12,5 mg	Tablet	Oral use
Sweden	AstraZeneca AB 151 85 Södertälje, Sweden	Atacand Plus	16 mg/12,5 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Sweden	AstraZeneca AB 151 85 Södertälje, Sweden	Atacand Plus	32 mg/12,5 mg	Tablet	Oral use
Sweden	AstraZeneca AB 151 85 Södertälje, Sweden	Atacand Plus	32 mg/25 mg	Tablet	Oral use
Sweden	Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, London, WC2B 4AE, United Kingdom	Blopress Comp	8 mg/12,5 mg	Tablet	Oral use
Sweden	Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, London, WC2B 4AE, United Kingdom	Blopress Comp	16 mg/12,5 mg	Tablet	Oral use
Sweden	Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, London, WC2B 4AE, United Kingdom	Blopress Comp	32 mg/12,5 mg	Tablet	Oral use
Sweden	Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, London, WC2B 4AE, United Kingdom	Blopress Comp	32 mg/25 mg	Tablet	Oral use
Sweden	Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, London, WC2B 4AE, United Kingdom	Parapres Comp Forte	16 mg/12,5 mg	Tablet	Oral use
Sweden	Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, London, WC2B 4AE, United Kingdom	Parapres Comp	32 mg/12,5 mg	Tablet	Oral use
Sweden	Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, London, WC2B 4AE, United Kingdom	Parapres Comp	32 mg/25 mg	Tablet	Oral use

ANNEX VI

LIST OF THE NAMES, PHARMACEUTICAL FORM(S), STRENGTH(S) OF THE MEDICINAL PRODUCT(S), ROUTE(S) OF ADMINISTRATION, APPLICANT(S) MARKETING AUTHORISATION HOLDER(S) IN THE MEMBER STATES

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Belgium	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet 50 microgram/0,5 mg/g gel	50 µg/g + 0,5 mg/g	Gel	Cutaneous use
Belgium	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet 50 microgram/g + 0,5 mg/g, zalf	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Bulgaria	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet®	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Cyprus	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet® 50 microgram/g + 0,5 mg/g ointment	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Czech Republic	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet mast	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Denmark	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet	50 µg/g + 0,5 mg/g	Gel	Cutaneous use
Denmark	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Estonia	LEO Pharmaceutical Products Industriparken 55 DK-2750 Ballerup Denmark	DAIVOBET	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Finland	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet 50 mikrogram/g + 0,5 mg/g geeli	50 µg/g + 0,5 mg/g	Gel	Cutaneous use
Finland	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet 50/500 mikrog/g voide	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
France	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	DAIVOBET 50 microgrammes/0,5 mg/g, gel	50 µg/g + 0,5 mg/g	Gel	Cutaneous use
France	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	DAIVOBET 50 microgrammes/0,5 mg/g, pommade	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Germany	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet 50 Mikrogramm/g + 0,5 mg/g Gel	50 µg/g + 0,5 mg/g	Gel	Cutaneous use
Germany	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet® 50 Mikrogramm/g + 0,5 mg/g Salbe	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Greece	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet 50 microgram/ 0,5 mg/g gel	50 µg/g + 0,5 mg/g	Gel	Cutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Greece	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet 50 microgram/g + 0,5 mg/g	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Hungary	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet ointment	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Iceland	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet 50 míkrógrömm/0,5 mg/g hlaup	50 µg/g + 0,5 mg/g	Gel	Cutaneous use
Iceland	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet 50 míkróg/g + 0,5 mg/g smyrsli	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Ireland	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet 50 microgram/g + 0,5 mg/g gel	50 µg/g + 0,5 mg/g	Gel	Cutaneous use
Ireland	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet 50 microgram/g + 0,5 mg/g ointment	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Italy	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet	50 µg/g + 0,5 mg/g	Gel	Cutaneous use
Italy	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Latvia	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet® 50 µg/g + 0,5 mg/g ziede	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Lithuania	LEO Pharmaceutical Products Industriparken 55 DK-2750 Ballerup Denmark	Daivobet	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Luxembourg	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet Scalp 50 microgram/0,5 mg/g gel	50 µg/g + 0,5 mg/g	Gel	Cutaneous use
Luxembourg	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet 50 microgrammes/g + 0,5 mg/g, onguent	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Malta	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet® 50 micrograms/g + 0,5 mg/g ointment	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Netherlands	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet gel 50 microgram/0,5 mg/g gel	50 µg/g + 0,5 mg/g	Gel	Cutaneous use
Netherlands	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet zalf 50 microgram/g + 0,5 mg/g	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Norway	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet 50 mikrogram/g + 0,5 mg/g gel	50 µg/g + 0,5 mg/g	Gel	Cutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Norway	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet 50 mikrogram/g + 0,5 mg/g salve	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Poland	LEO Pharmaceutical Products Ltd. A/S Industriparken 55 DK-2750 Ballerup Denmark	DAIVOBET	(50 µg + 0,5 mg)/g	Ointment	Cutaneous use
Portugal	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet	50 µg/g + 0,5 mg/g	Gel	Cutaneous use
Portugal	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Romania	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	DAIVOBET® UNGUENT	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Slovenia	Pharmagan, d.o.o. Vodopivceva 9 SI-4000 Kranj Slovenia	Daivobet 50 mikrogramov/500 mikrogramov v 1 g mazilo	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
Spain	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet 50 microgramos/g + 0,5 mg/g gel	50 µg/g + 0,5 mg/g	Gel	Cutaneous use
Spain	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet 50 microgramos/g + 0,5 mg/g pomada	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Sweden	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet	50 µg/g + 0,5 mg/g	Gel	Cutaneous use
Sweden	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Daivobet	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use
United Kingdom	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet 50 microgram/g + 0,5 mg/g gel	50 µg/g + 0,5 mg/g	Gel	Cutaneous use
United Kingdom	LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) Industriparken 55 DK-2750 Ballerup Denmark	Dovobet® 50 microgram/g + 0,5 mg/g ointment	50 µg/g + 0,5 mg/g	Ointment	Cutaneous use

ANNEX VII

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANT AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing authorisation holder	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Italy		Warner Chilcott UK Limited, Old Belfast Road, Millbrook, Larne, County Antrim, BT40 2SH United Kingdom	Actocalcio D3	35 mg + 1 000 mg/880 IU	film-coated tablets + effervescent granules	Oral use
Spain	PROCTER AND GAMBLE PHARMACEUTICALS IBERIA, S.L. WTC Almeda Park, Ed. 1, 2ª pl. Plaça de la Pau s/n 08940 Cornellà de Llobregat (Barcelona) Spain		Acrelcombi	35 mg + 1 000 mg/880 IU	film-coated tablets + effervescent granules	Oral use
Sweden	Warner Chilcott UK Limited, Old Belfast Road, Millbrook, Larne, County Antrim, BT40 2SH United Kingdom		Fortipan Combi D	35 mg + 1 000 mg/880 IU	film-coated tablets + effervescent granules	Oral use

ANNEX VIII

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	Pfizer Corporation Austria GmbH Floridsdorfer Hauptstraße 1 A-1210 Wien Austria	Genotropin 12 mg - Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	12 mg	Powder and solvent for solution for injection	Subcutaneous use
Austria	Pfizer Corporation Austria GmbH Floridsdorfer Hauptstraße 1 A-1210 Wien Austria	Genotropin 5,3 mg - Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	5,3 mg	Powder and solvent for solution for injection	Subcutaneous use
Austria	Pfizer Corpoation Austria GmbH Floridsdorfer Hauptstraße 1 A-1210 Wien Austria	Genotropin MiniQuick 0,2 mg - Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	0,2 mg	Powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm	1,3 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm	5,0 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm	5,3 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm	12 mg	powder and solvent for solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	0,2 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	0,4 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	0,6 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	0,8 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	1,0 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	1,2 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	1,4 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	1,6 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	1,8 mg	powder and solvent for solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	2,0 mg	powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin	1,3 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin	5 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin	5,3 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin	12 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	0,2 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	0,4 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	0,6 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	0,8 mg	Powder and solvent for solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	1,0 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	1,2 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	1,4 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	1,6 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	1,8 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	2,0 mg	Powder and solvent for solution for injection	Subcutaneous use
Finland	Pfizer Oy, Tietokuja 4, 00330 Helsinki, Finland	Genotropin	5 mg	Powder and solvent for solution for injection	Subcutaneous use
Finland	Pfizer Oy, Tietokuja 4, 00330 Helsinki, Finland	Genotropin	12 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM 5 mg, poudre et solvant pour solution injectable	5 mg	Powder and solvent for solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM 5,3 mg, poudre et solvant pour solution injectable	5,3 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM 12 mg, poudre et solvant pour solution injectable	12 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 0,2 mg, poudre et solvant pour solution injectable	0,2 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 0,4 mg, poudre et solvant pour solution injectable	0,4 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 0,6 mg, poudre et solvant pour solution injectable	0,6 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 0,8 mg, poudre et solvant pour solution injectable	0,8 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 1 mg, poudre et solvant pour solution injectable	1 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 1,2 mg, poudre et solvant pour solution injectable	1,2 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 1,4 mg, poudre et solvant pour solution injectable	1,4 mg	Powder and solvent for solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 1,6 mg, poudre et solvant pour solution injectable	1,6 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 1,8 mg, poudre et solvant pour solution injectable	1,8 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 2 mg, poudre et solvant pour solution injectable	2 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	Genotropin 5 mg/ml	5,0 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	Genotropin 5,3 mg/ml	5,3 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	Genotropin 12 mg/ml	12,0 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 0,2 mg	0,2 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 0,4 mg	0,4 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 0,6 mg	0,6 mg	Powder and solvent for solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 0,8 mg	0,8 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 1,0 mg	1,0 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 1,2 mg	1,2 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 1,4 mg	1,4 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 1,6 mg	1,6 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin	GENOTROPIN MiniQuick 1,8 mg	1,8 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 2,0 mg	2,0 mg	Powder and solvent for solution for injection	Subcutaneous use
Greece	PFIZER HELLAS A.E. MESSOGHION AVE. 243 15451 NEO PSYCHIKO Greece	GENOTROPIN	1 mg	Powder and Solution for solution for injection	Subcutaneous use
Greece	PFIZER HELLAS A.E. MESSOGHION AVE. 243 15451 NEO PSYCHIKO Greece	GENOTROPIN	1,4 mg	Powder and Solution for solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Greece	PFIZER HELLAS A.E. MESSOGHION AVE. 243 15451 NEO PSYCHIKO Greece	GENOTROPIN	2 mg	Powder and Solution for solution for injection	Subcutaneous use
Greece	PFIZER HELLAS A.E. MESSOGHION AVE. 243 15451 NEO PSYCHIKO Greece	GENOTROPIN	5 mg	Powder and Solution for solution for injection	Subcutaneous use
Greece	PFIZER HELLAS A.E. MESSOGHION AVE. 243 15451 NEO PSYCHIKO Greece	GENOTROPIN (WITH PRESERVATIVE)	5,3 mg	Powder and Solution for solution for injection	Subcutaneous use
Greece	PFIZER HELLAS A.E. MESSOGHION AVE. 243 15451 NEO PSYCHIKO Greece	GENOTROPIN (WITH PRESERVATIVE)	12 mg	Powder and Solution for solution for injection	Subcutaneous use
Greece	PFIZER HELLAS A.E. MESSOGHION AVE. 243 15451 NEO PSYCHIKO Greece	GENOTROPIN	1,3 mg	Powder and Solution for solution for injection	Subcutaneous use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN 5,3 MG	5,3 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN 12 MG	12 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0,2 MG	0,2 mg	Powder and solvent for Solution for injection	Subcutaneous Use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0,4 MG	0,4 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0,6 MG	0,6 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0,8 MG	0,8 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1 MG	1 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1,2 MG	1,2 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1,4 MG	1,4 mg	Powder and solvent for Solution for injection	Subcutaneous Use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1,6 MG	1,6 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1,8 MG	1,8 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 2 MG	2 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin	5,3 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin	12 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	0,2 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	0,4 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	0,6 mg	powder and solvent for solution for injection	subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	0,8 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	1 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	1,2 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	1,4 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	1,6 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	1,8 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	2 mg	powder and solvent for solution for injection	subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm	1,3 mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm	5 mg	powder and solvent for solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm	5,3 mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm	12 mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	0,2 mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	0,4 mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	0,6 mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	0,8 mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	1 mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	1,2 mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	1,4 mg	powder and solvent for solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	1,6 mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	1,8 mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	2 mg	powder and solvent for solution for injection	Subcutaneous use
Netherlands	Pfizer BV Postbus 37 2900AA Capelle aan den Ijssel The Netherlands	Genotropin 5 mg, poeder en oplosmiddel voor oplossing voor injectie	5 mg	powder and solvent for solution for injection	Subcutaneous use
Netherlands	Pfizer BV Postbus 37 2900AA Capelle aan den Ijssel The Netherlands	Genotropin 12 mg, poeder en oplosmiddel voor oplossing voor injectie	12 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin 1,3 mg	1,3 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin 12 mg	12 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin 5,3 mg	5,3 mg	powder and solvent for solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Mixer	5,3 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	1 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	2 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	0,2 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	0,4 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	0,6 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	0,8 mg	powder and solvent for solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	1,2 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	1,4 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	1,6 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	1,8 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Mixer	1,3 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin	5 mg	powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM KABIPEN 12 mg polvo y disolvente para solución inyectable	12 mg	Powder and solvent for solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM KABIPEN 5,3 mg polvo y disolvente para solución inyectable	5,3 mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 0,2 mg polvo y disolvente para solución inyectable	0,2 mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 0,4 mg polvo y disolvente para solución inyectable	0,4 mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 0,6 mg polvo y disolvente para solución inyectable	0,6 mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 0,8 mg polvo y disolvente para solución inyectable	0,8 mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 1 mg polvo y disolvente para solución inyectable	1 mg	Powder and solvent for solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 1,2 mg polvo y disolvente para solución inyectable	1,2 mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 1,4 mg polvo y disolvente para solución inyectable	1,4 mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 1,6 mg polvo y disolvente para solución inyectable	1,6 mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 1,8 mg polvo y disolvente para solución inyectable	1,8 mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 2 mg polvo y disolvente para solución inyectable	2 mg	Powder and solvent for solution for injection	Subcutaneous use
Sweden	Pfizer AB, 191 90 Sollentuna, Sverige Sweden	Genotropin	5,3 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB, 191 90 Sollentuna, Sverige Sweden	Genotropin	12 mg	Powder and solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Sweden	Pfizer AB, 191 90 Sollentuna, Sverige Sweden	Genotropin	5 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB, 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	0,2 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB, 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	0,4 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB, 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	0,6 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB, 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	0,8 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB, 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	1 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB, 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	1,2 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB, 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	1,4 mg	Powder and solution for injection	Subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Sweden	Pfizer AB, 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	1,6 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB, 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	1,8 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB, 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	2 mg	Powder and solution for injection	Subcutaneous use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ	GENOTROPIN 5,3 MG	5,3 mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN 12 MG	12 mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0,2 MG	0,2 mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0,4 MG	0,4 mg	Powder and solvent for solution for injection	Subcutaneous Use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0,6 MG	0,6 mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0,8 MG	0,8 mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1 MG	1 mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1,2 MG	1,2 mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1,4 MG	1,4 mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1,6 MG	1,6 mg	Powder and solvent for solution for injection	Subcutaneous Use

Member State EU/EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1,8 MG	1,8 mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 2 MG	2 mg	Powder and solvent for solution for injection	Subcutaneous Use

ANNEX IX

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE VETERINARY MEDICINAL PRODUCT, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	Product name	Pharmaceutical form	Strength	Target animal species	Route of administration
Belgium	Pfizer Animal Health Rue Laid Burniat 1 1348 - Louvain-la-Neuve BELGIUM	PREGSURE BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Bulgaria	Pfizer Animal Health MA EEIG Ramsgate Road Sandwich, Kent CT13 9NJ UNITED KINGDOM	PregSure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Czech Republic	Pfizer, spol. s r.o. Stroupežnického 17 150 00 Praha CZECH REPUBLIC	PregSure BVD injekční emulze	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Estonia	Pfizer Animal Health Rue Laid Burniat 1 1348 - Louvain-la-Neuve BELGIUM	PregSure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
France	PFIZER 23/25 Avenue du Docteur Lannelongue 75014 Paris FRANCE	PREGSURE BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Germany	Pfizer GmbH Linkstraße 10 D-10785 Berlin GERMANY	PregSure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Greece	PFIZER HELLAS S.A 243 Messogeion Ave. Neo Psychiko GR-154 51 GREECE	PREGSURE BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous

Member State	Marketing Authorisation Holder	Product name	Pharmaceutical form	Strength	Target animal species	Route of administration
Hungary	Pfizer Kft. Alkotas u 53 MOM Park 'F' Épület Budapest H-1123 HUNGARY	PregSure BVD vakcina A.U.V.	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Ireland	Pfizer Healthcare Ireland trading as Pfizer Animal Health Ringaskiddy County Cork IRELAND	PregSure BVD Emulsion for Injection	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Italy	Pfizer Italia Srl Via Isonzo 71 04100 – Latina ITALY	Pregsure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Lithuania	Pfizer Animal Health S.A. Rue Laid Burniat 1 B-1348 - Louvain-la-Neuve BELGIUM	PREGSURE BVD, injekcinė emulsija	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Latvia	Pfizer Ltd Ramsgate Road Sandwich, Kent CT13 9NJ UNITED KINGDOM	PregSure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Poland	Pfizer Trading Polska Sp. z o.o. ul. Rzymowskiego 34 02-697 Warszawa POLAND	PregSure BVD emulsja do wstrzykiwań	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Portugal	Laboratórios Pfizer Lda Lagoas Park – Edifício 10 2740-244 Porto Salvo PORTUGAL	Pregsure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous

Member State	Marketing Authorisation Holder	Product name	Pharmaceutical form	Strength	Target animal species	Route of administration
Romania	Pfizer Animal Health MA EEIG Ramsgate Road, Sandwich, Kent CT 13 9NJ UNITED KINGDOM	Pregsure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Slovenia	Pfizer Luxembourg SARL Gran Duchy of Luxembourg 51, Avenue J.F. Kennedy L-1855 - Luxembourg	Pregsure BVD emulzija za injiciranje	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Slovak republic	Pfizer Luxembourg SARL o.z. Pfizer AH Pribinova 25 81109 Bratislava SLOVAK REPUBLIC	Pregsure BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
Spain	Pfizer SA Avda. De Europa, 20 B Parque Empresarial la Moraleja (Alcobendas) 28108 SPAIN	PREGSURE BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
The Netherlands	Pfizer Animal Health BV Rivium Westlaan 142 2909 LD Capelle a/d Ijssel P.O. Box 37 2900 AA Capelle a/d Ijssel THE NETHERLANDS	PREGSURE BVD	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous
United Kingdom	Pfizer Ltd Ramsgate Road Sandwich, Kent CT13 9NJ UNITED KINGDOM	Pregsure BVD Emulsion for Injection	Emulsion for injection	to induce a geometric mean seroneutralizing titre in guinea pigs of at least 5.6 log2	Cattle at breeding age (cows and heifers)	Subcutaneous

ANNEX X

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
AT - Austria	Octapharma Pharmazeutika Produktionsgesellschaft m.b.H. Oberlaaerstraße 235 A-1100 Wien Austria	Octagam 100 mg/ml Infusionslösung	100 mg/ml	Solution for infusion	Intravenous Use
AT - Austria	Octapharma Pharmazeutika Produktionsgesellschaft m.b.H. Oberlaaerstraße 235 A-1100 Wien Austria	Octagam 50 mg/ml Infusionslösung	50 mg/ml	Solution for infusion	Intravenous Use
BE - Belgium	OCTAPHARMA BENELUX SA Rue de Stalle 63 1180 Bruxelles (Brussels) Belgium	Octagam 10 %, solution pour perfusion	10 % (100 mg/ml)	Solution for infusion	Intravenous Use
BE - Belgium	OCTAPHARMA BENELUX SA Rue de Stalle 63 1180 Bruxelles (Brussels) Belgium	Octagam 50 mg/ml solution pour perfusion	50 mg/ml	Solution for infusion	Intravenous Use
BG - Bulgaria	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam 10 %	100 mg/ml	Solution for infusion	Intravenous Use
CY - Cyprus	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	OCTAGAM INFUSION 10 %	10 %	Solution for infusion	Intravenous use
CY - Cyprus	Hospitec Co Ltd 5 Thessalonikis, Block B 2085 Lefkosia Cyprus	OCTAGAM INFUSION 5 %	5 %	Solution for infusion	Intravenous use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
CZ - Czech Republic	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	OCTAGAM	50 mg/ml	Solution for infusion	Intravenous Use
CZ - Czech Republic	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	OCTAGAM 10 %	100 mg/ml	Solution for infusion	Intravenous Use
DE - Germany	OCTAPHARMA GmbH Elisabeth-Selbert-Str. 11 40764 Langenfeld Germany	Octagam 50 mg/ml	50 mg/ml	Solution for infusion	Intravenous Use
DE - Germany	OCTAPHARMA GmbH Elisabeth-Selbert-Str. 11 40764 Langenfeld Germany	Octagam 5 %	50 mg/ml	Solution for infusion	Intravenous Use
DE - Germany	OCTAPHARMA GmbH Elisabeth-Selbert-Str. 11 40764 Langenfeld Germany	Octagam 10 %	100 mg/ml	Solution for infusion	Intravenous Use
DK - Denmark	Octapharma AB Elersvägen 40 SE-11275 Stockholm Sweden	Octagam	50 mg/ml	Solution for infusion	Intravenous Use
DK - Denmark	Octapharma AB Elersvägen 40 SE-11275 Stockholm Sweden	Octagam	100 mg/ml	Solution for infusion	Intravenous Use
EL - Greece	Octapharma Hellas SA George Kalbitzer 60, posidonos Ave. 166 75 Glyfada Attiki Greece	OCTAGAM	5 % (W/V)	Solution for infusion	Intravenous Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
EL - Greece	Octapharma Hellas SA George Kalbitzer 60, posidonos Ave. 166 75 Glyfada Attiki Greece	OCTAGAM	10 % (100MG/ML)	Solution for infusion	Intravenous Use
ES - Spain	OCTAPHARMA, S.A. C/ Velázquez, 150 28002 Madrid ESPAÑA	Octagamocta 100 mg/ml solución para perfusión	100 mg/ml	Solution for infusion	Intravenous use
ES - Spain	OCTAPHARMA, S.A. C/ Velázquez, 150 28002 Madrid ESPAÑA	Octagamocta 50 mg/ml solución para perfusión	50 mg/ml	Solution for infusion	Intravenous use
ET - Estonia	Octapharma AB Elersvägen 40 SE-11275 Stockholm Sweden	OCTAGAM	50 mg/ml	Solution for infusion	Intravenous Use
ET - Estonia	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	OCTAGAM 10 %	100 mg/1ml	Solution for infusion	Intravenous Use
FI - Finland	OCTAPHARMA Rajatorpantie 41 C 01640 Vantaa FINLAND	OCTAGAM	50 mg/ml 100 mg/ml	Solution for infusion	Intravenous Use
FR - France	Octapharma France SAS Laurent de Narbonne 62Bis Avenue André Morizet F- 92100 Boulogne Billancourt France	OCTAGAM 100 mg/ml, solution pour perfusion	100 mg/ml	Solution for infusion	Intravenous Use
FR - France	Octapharma France SAS Laurent de Narbonne 62Bis Avenue André Morizet F- 92100 Boulogne Billancourt France	OCTAGAM 50 mg/ml, solution pour perfusion	50 mg/ml	Solution for infusion	Intravenous Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
HU - Hungary	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	OCTAGAM 50 mg/ml oldatos infúzió	50 mg/ml	Solution for infusion	Intravenous Use
HU - Hungary	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	OCTAGAM 100 mg/ml oldatos infúzió	100 mg/ml	Solution for infusion	Intravenous Use
IS - Iceland	Octapharma AB Nordenflychtsvägen 55 SE-112 75 Stockholm Sweden	Octagam 5 %	50 mg/ml	Solution for infusion	Intravenous Use
IS - Iceland	Octapharma AB Nordenflychtsvägen 55 SE-112 75 Stockholm Sweden	Octagam 10 %	100 mg/ml	Solution for infusion	Intravenous Use
IT - Italy	Octapharma Ltd The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	OCTAGAM	5 %	Solution for infusion	Intravenous Use
LT - Lithuania	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	octagam	100 mg/ml	Solution for infusion	Intravenous Use
LU - Luxembourg	OCTAPHARMA BENELUX SA Rue de Stalle 63 1180 Bruxelles (Brussels) Belgium	Octagam	5 %	Solution for infusion	Intravenous use
LU - Luxembourg	OCTAPHARMA BENELUX SA Rue de Stalle 63 1180 Bruxelles (Brussels) Belgium	Octagam-10	10 %	Solution for infusion	Intravenous use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
LV - Latvia	Octapharma AB Elesvagen 40 Stockholm, S-112 75 Sweden	Octagam 50 mg/ml solution for infusion	1 g/20 ml	Solution for infusion	Intravenous Use
LV - Latvia	Octapharma AB Elesvagen 40 Stockholm, S-112 75 Sweden	Octagam 50 mg/ml solution for infusion	2,5 g/50 ml	Solution for infusion	Intravenous Use
LV - Latvia	Octapharma AB Elesvagen 40 Stockholm, S-112 75 Sweden	Octagam 50 mg/ml solution for infusion	5 g/100 ml	Solution for infusion	Intravenous Use
LV - Latvia	Octapharma AB Elesvagen 40 Stockholm, S-112 75 Sweden	Octagam 50 mg/ml solution for infusion	10 g/200 ml	Solution for infusion	Intravenous Use
LV - Latvia	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam 100 mg/ml šķīdums infūzijām, 2 g/ 20 ml	2 g/20 ml	Solution for infusion	Intravenous Use
LV - Latvia	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam 100 mg/ml šķīdums infūzijām, 5 g/ 50 ml	5 g/50 ml	Solution for infusion	Intravenous Use
LV - Latvia	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam 100 mg/ml šķīdums infūzijām, 10 g/ 100 ml	10 g/100 ml	Solution for infusion	Intravenous Use
LV - Latvia	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam 100 mg/ml šķīdums infūzijām, 20 g/ 200 ml	20 g/200 ml	Solution for infusion	Intravenous Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
MT - Malta	Octapharma (IP) Limited, The Zenith Building, 26 Spring Gardens, Manchester M2 1AB, United Kingdom	OCTAGAM 10 %	1ml contains: protein 100mg (of which ≥ 95 % is human Immunoglobulin G), IgA ≤ 0,4 mg, IgM ≤ 0,3mg	Solution for infusion	Intravenous use
NL - Netherlands	Octapharma GmbH Reinhard Rettinghaus Elisabeth-Selbert-Str. 11 40764 Langenfeld Germany	Octagam 10 %	100 mg/ml	Solution for infusion	Intravenous Use
NL - Netherlands	Octapharma GmbH Reinhard Rettinghaus Elisabeth-Selbert-Str. 11 40764 Langenfeld Germany	Octagam 5 %	50 mg/ml	Solution for infusion	Intravenous Use
NO - Norway	Octapharma AG Kim Björnstrup Seidenstraße 2 CH-8853 Lachen Switzerland	Octagam	50 mg/ml	Solution for infusion	Intravenous Use
NO - Norway	Octapharma AG Kim Björnstrup Seidenstraße 2 CH-8853 Lachen Switzerland	Octagam	100 mg/ml	Solution for infusion	Intravenous Use
PL - Poland	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam	2,5 g/50 ml	Solution for infusion	Intravenous Use
PL - Poland	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam	5 g/100 ml	Solution for infusion	Intravenous Use
PL - Poland	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam 10 %	20 g/200 ml	Solution for infusion	Intravenous Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
PL - Poland	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam 10 %	100 mg/ml	Solution for infusion	Intravenous Use
PT - Portugal	Octapharma Produtos Farmaceuticos, Lda. Paulo Castro Rua da Graca, 14 P-1170-169 Lisboa Portugal	Octagam	50 mg/ml	Solution for infusion	Intravenous use
PT - Portugal	Octapharma Produtos Farmaceuticos, Lda. Paulo Castro Rua da Graca, 14 P-1170-169 Lisboa Portugal	Octagam	100 mg/ml	Solution for infusion	Intravenous use
RO - Romania	OCTAPHARMA (IP) Ltd. The Zenith Building 26 Spring Gardens Manchester, M2 1AB United Kingdom	OCTAGAM	50 mg/ml	Solution for infusion	Intravenous use
RO - Romania	OCTAPHARMA (IP) Ltd. The Zenith Building 26 Spring Gardens Manchester, M2 1AB United Kingdom	OCTAGAM 10 %	100 mg/ml	Solution for infusion	Intravenous use
SE - Sweden	Octapharma AB Olivier Clairotte Elersvägen 40 SE-11275 Stockholm Sweden	Octagem	50 mg/ml	Solution for infusion	Intravenous use
SE - Sweden	Octapharma AB Olivier Clairotte Elersvägen 40 SE-11275 Stockholm Sweden	Octagem	100 mg/ml	Solution for infusion	Intravenous use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
SI - Slovenia	Zavod Republike Slovenije za transfuzijsko medicino Šlajmerjeva 6 1000 Ljubljana Slovenija	Octagam 50 mg/ml raztopina za infundiranje	50 mg/ ml	Solution for infusion	Intravenous use
SI - Slovenia	Zavod Republike Slovenije za transfuzijsko medicino Šlajmerjeva 6 1000 Ljubljana Slovenija	Octagam 100 mg/ml raztopina za infundiranje	100 mg/ml	Solution for infusion	Intravenous use
SK - Slovakia	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam	20 ml 50 mg/ml	Solution for infusion	Intravenous use
SK - Slovakia	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam	50 ml 50 mg/ml	Solution for infusion	Intravenous use
SK - Slovakia	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam	100 ml 50 mg/ml	Solution for infusion	Intravenous use
SK - Slovakia	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam	200 ml 50 mg/ml	Solution for infusion	Intravenous use
SK - Slovakia	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam 10 %	20 ml 100 mg/ml	Solution for infusion	Intravenous use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
SK - Slovakia	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam 10 %	50 ml 100 mg/ml	Solution for infusion	Intravenous use
SK - Slovakia	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam 10 %	100 ml 100 mg/ml	Solution for infusion	Intravenous use
SK - Slovakia	Octapharma (IP) Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam 10 %	200 ml 100 mg/ml	Solution for infusion	Intravenous use
UK - United Kingdom	Octapharma Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam Infusion	5 % w/v	Solution for infusion	Intravenous use
UK - United Kingdom	Octapharma Limited The Zenith Building 26 Spring Gardens Manchester M2 1AB United Kingdom	Octagam 10 % solution for Infusion	10 % w/v	Solution for infusion	Intravenous use

2010 SUBSCRIPTION PRICES (excluding VAT, including normal transport charges)

EU Official Journal, L + C series, paper edition only	22 official EU languages	EUR 1 100 per year
EU Official Journal, L + C series, paper + annual CD-ROM	22 official EU languages	EUR 1 200 per year
EU Official Journal, L series, paper edition only	22 official EU languages	EUR 770 per year
EU Official Journal, L + C series, monthly CD-ROM (cumulative)	22 official EU languages	EUR 400 per year
Supplement to the Official Journal (S series), tendering procedures for public contracts, CD-ROM, two editions per week	multilingual: 23 official EU languages	EUR 300 per year
EU Official Journal, C series — recruitment competitions	Language(s) according to competition(s)	EUR 50 per year

Subscriptions to the *Official Journal of the European Union*, which is published in the official languages of the European Union, are available for 22 language versions. The Official Journal comprises two series, L (Legislation) and C (Information and Notices).

A separate subscription must be taken out for each language version.

In accordance with Council Regulation (EC) No 920/2005, published in Official Journal L 156 of 18 June 2005, the institutions of the European Union are temporarily not bound by the obligation to draft all acts in Irish and publish them in that language. Irish editions of the Official Journal are therefore sold separately.

Subscriptions to the Supplement to the Official Journal (S Series — tendering procedures for public contracts) cover all 23 official language versions on a single multilingual CD-ROM.

On request, subscribers to the *Official Journal of the European Union* can receive the various Annexes to the Official Journal. Subscribers are informed of the publication of Annexes by notices inserted in the *Official Journal of the European Union*.

CD-Rom formats will be replaced by DVD formats during 2010.

Sales and subscriptions

Subscriptions to various priced periodicals, such as the subscription to the *Official Journal of the European Union*, are available from our commercial distributors. The list of commercial distributors is available at:

http://publications.europa.eu/others/agents/index_en.htm

EUR-Lex (http://eur-lex.europa.eu) offers direct access to European Union legislation free of charge. The *Official Journal of the European Union* can be consulted on this website, as can the Treaties, legislation, case-law and preparatory acts.

For further information on the European Union, see: http://europa.eu

Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

EN