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(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 2016 to 30 September 2016

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

(2016/C 399/01)

([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
9.9.2016	CABOMETYX	cabozantinib	Ipsen Pharma 65 quai Georges Gorse, F-92100 Boulogne-Billancourt, France	EU/1/16/1136	Film-coated tablet	L01XE26	13.9.2016
15.9.2016	Inhixa	enoxaparin sodium	Techdow Europe AB Banérgatan 36, 75237 Uppsala, Sverige	EU/1/16/1132	Solution for injection	B01AB05	19.9.2016
15.9.2016	Mysildecard	sildenafil	Mylan S.A.S 117 allée des Parcs, F-69800 Saint Priest, France	EU/1/16/1134	Film-coated tablet	G04BE03	19.9.2016
15.9.2016	Sialanar	glycopyrronium bromide	Proveca Limited Daresbury Innovation Centre, Keckwick Lane, Daresbury, Halton, Cheshire, WA4 4FS, United Kingdom	EU/1/16/1135	Oral solution	A03AB02	19.9.2016
15.9.2016	Tenofovir disoproxil Zentiva	tenofovir disoproxil	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/16/1127	Film-coated tablet	J05AF07	19.9.2016
15.9.2016	Thorinane	enoxaparin sodium	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/16/1131	Solution for injection	B01AB05	19.9.2016
19.9.2016	Truberzi	eluxadoline	Aptalis Pharma SAS 5/6 Place de l'Iris — La Défense 5 92400 Courbevoie France	EU/1/16/1126	Film-coated tablet	Pending	21.9.2016

— **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
2.9.2016	Enzepi	Allergan Pharmaceuticals International Limited, Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland	EU/1/16/1113	6.9.2016
2.9.2016	Extavia	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/08/454	6.9.2016
2.9.2016	Kengrexal	Chiesi Farmaceutici S.P.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/15/994	6.9.2016
2.9.2016	Ofev	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/979	6.9.2016
5.9.2016	Nimvastid	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/525	7.9.2016
8.9.2016	Betaferon	Bayer Pharma AG D-13342 Berlin, Deutschland	EU/1/95/003	12.9.2016
8.9.2016	Budesonide/Formoterol Teva Pharma B.V.	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	EU/1/14/950	12.9.2016
8.9.2016	Caprelsa	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/11/749	12.9.2016
8.9.2016	DUAVIVE	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/14/960	12.9.2016
8.9.2016	Insulatard	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/233	12.9.2016
8.9.2016	Levetiracetam Actavis	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Ísland	EU/1/11/713	12.9.2016
8.9.2016	Lucentis	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/06/374	12.9.2016
8.9.2016	Panretin	Eisai Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire AL10 9SN, United Kingdom	EU/1/00/149	12.9.2016
8.9.2016	Plegridy	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/14/934	12.9.2016
8.9.2016	Protaphane	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/234	12.9.2016

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
9.9.2016	Ameluz	Biofrontera Bioscience GmbH Hemmelrather Weg 201, D-51377 Leverkusen, Deutschland	EU/1/11/740	13.9.2016
9.9.2016	Efavirenz Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/742	13.9.2016
9.9.2016	Elaprase	Shire Human Genetic Therapies AB Vasagatan 7, 111 20 Stockholm, Sverige	EU/1/06/365	13.9.2016
9.9.2016	Eurartesim	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A Viale Shakespeare 47, 00144 Roma, Italia	EU/1/11/716	13.9.2016
9.9.2016	Laventair	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/14/899	16.9.2016
9.9.2016	Revlimid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/07/391	13.9.2016
9.9.2016	Tandemact	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/06/366	13.9.2016
9.9.2016	Tracleer	Actelion Registration Ltd Chiswick Tower, 13th floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/220	13.9.2016
9.9.2016	Velphoro	Vifor Fresenius Medical Care Renal Pharma France 7-13 boulevard Paul-Emile Victor, 92521 Neuilly-sur-Seine, France	EU/1/14/943	15.9.2016
9.9.2016	Xolair	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/05/319	13.9.2016
15.9.2016	Arava	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/99/118	19.9.2016
15.9.2016	Arixtra	Aspen Pharma Trading Limited 3016 Lake Drive Citywest Business Campus Dublin 24 Ireland	EU/1/02/206	19.9.2016
15.9.2016	Evoltra	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/06/334	19.9.2016
15.9.2016	Fosavance	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/05/310	19.9.2016
15.9.2016	Ganfort	Allergan Pharmaceuticals Ireland, (514125) Castlebar Road, Westport, County Mayo, Ireland	EU/1/06/340	19.9.2016
15.9.2016	Ibandronic Acid Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/642	19.9.2016

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
15.9.2016	Intelence	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/08/468	19.9.2016
15.9.2016	PANTECTA Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/518	19.9.2016
15.9.2016	Trulicity	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/14/956	19.9.2016
15.9.2016	Zydelig	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/14/938	19.9.2016
16.9.2016	Lamivudine Teva Pharma B.V.	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/596	20.9.2016
19.9.2016	Adrovance	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/364	21.9.2016
19.9.2016	Enbrel	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/99/126	21.9.2016
19.9.2016	Fycompa	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Herts AL10 9SN, United Kingdom	EU/1/12/776	21.9.2016
19.9.2016	Repaglinide Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, Harrow, HA1 4HF, United Kingdom	EU/1/11/743	21.9.2016
19.9.2016	Soliris	Alexion Europe SAS 1-15 avenue Edouard Belin, 92500 Rueil-Malmaison, France	EU/1/07/393	21.9.2016
19.9.2016	Sovaldi	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/13/894	21.9.2016
19.9.2016	Vantavo	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/09/572	21.9.2016
19.9.2016	Zydelig	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/14/938	21.9.2016
22.9.2016	Anoro	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/14/898	26.9.2016
22.9.2016	Blincyto	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/15/1047	26.9.2016
22.9.2016	EVARREST	Omrix Biopharmaceuticals N.V. Leonardo Da Vincilaan 15, B-1831 Diegem, België	EU/1/13/868	26.9.2016

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
22.9.2016	Instanyl	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/09/531	26.9.2016
22.9.2016	Leflunomide ratiopharm	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/10/654	26.9.2016
22.9.2016	Pregabalin Sandoz GmbH	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	EU/1/15/1012	26.9.2016
22.9.2016	Saxenda	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/15/992	26.9.2016
22.9.2016	Stayveer	Marklas Nederland B.V. Beneluxlaan 2b, NL-3446 GR Woerden, Nederland	EU/1/13/832	26.9.2016
22.9.2016	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529	26.9.2016
22.9.2016	Zelboraf	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/12/751	26.9.2016
26.9.2016	Colobreathe	Forest Laboratories UK Ltd. Whiddon Valley Barnstaple, North Devon, EX32 8NS, United Kingdom	EU/1/11/747	28.9.2016
26.9.2016	Tivicay	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/13/892	28.9.2016
30.9.2016	Cometriq	Ipsen Pharma 65 quai Georges Gorse, F-92100 Boulogne-Billancourt, France	EU/1/13/890	4.10.2016
30.9.2016	Moventig	Kyowa Kirin Limited Galabank Business Park, Galashiels, TD1 1QH, United Kingdom	EU/1/14/962	4.10.2016
30.9.2016	Vantobra	PARI Pharma GmbH Moosstrasse 3, D-82319 Starnberg, Deutschland	EU/1/14/932	4.10.2016

— **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
19.9.2016	PANTECTA Control	Takeda GmbH, (HRB 701016) Byk-Gulden-Str. 2, D-78467 Konstanz, Deutschland	EU/1/09/518	21.9.2016

— **Issuing 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	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
22.9.2016	ERAVAC	rabbit haemorrhagic disease vaccine (inactivated)	Laboratorios Hipra, S.A. Avda. La Selva, 135, E-17170 Amer (Girona), España	EU/2/16/199	Emulsion for injection	QI08AA	26.9.2016

— **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
19.9.2016	Reconcile	Nexcyon Pharmaceuticals Ltd First Floor Denmark House, 143 High Street, Chalfont St Peter SL9 9QL, United Kingdom	EU/2/08/080	29.9.2016
28.9.2016	Coliprotec F4	Prevtec Microbia GmbH Geyerspergerstr 27, 80689 München, Deutschland	EU/2/14/180	30.9.2016

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

European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 September 2016 to 30 September 2016

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

(2016/C 399/02)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
8.9.2016	Alkem Art 31	Not applicable	See Annex II	See Annex II	9.9.2016
22.9.2016	Durogesic and associated names — Art 30	fentanyl	See Annex III	See Annex III	23.9.2016
22.9.2016	Semler Art 31	Not applicable	See Annex IV	See Annex IV	23.9.2016

— Refusal of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
22.9.2016	Diclofenac epolamine 50 mg tablets — Art 29	diclofenac	See Annex I	See Annex I	23.9.2016

— Suspension of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
8.9.2016	Alkem Art 31	Not applicable	See Annex II	See Annex II	9.9.2016
22.9.2016	Semler Art 31	Not applicable	See Annex IV	See Annex IV	23.9.2016

[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 forms, strengths of the medicinal products, routes of administration, applicants in the member states

Member State EU/EEA	Applicant company name, address	Invented Name	Strength	Pharmaceutical form	Route of administration
Czech Republic	ALTERGON ITALIA S.r.L Via dell'Industria 83030 Pietradefusi, Avellino, ITALY	DICLOFENAC ALTERGON 50 MG TABLETY	50 mg	tablet	Oral use
France	ALTERGON ITALIA S.r.L Via dell'Industria 83030 Pietradefusi, Avellino, ITALY	DICLOFENAC ALTERGON	50 mg	tablet	Oral use
Slovak Republic	ALTERGON ITALIA S.r.L Via dell'Industria 83030 Pietradefusi, Avellino, ITALY	Diclofenac ALTERGON 50 mg	50 mg	tablet	Oral use
United Kingdom	ALTERGON ITALIA S.r.L Via dell'Industria 83030 Pietradefusi, Avellino, ITALY	DICLOFENAC EPOLAMINE ALTERGON 50 MG TABLETS	50 mg	tablet	Oral use

ANNEX II

List of nationally authorised medicinal products and marketing authorisation applications

Annex IA: Medicinal products recommended for maintenance and marketing authorisation applications for which bioequivalence vis-à-vis the EU reference medicinal product has been established

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Austria	Krka d.d., Novo mesto		Cefuroxim Krka 250 mg Filmtabletten	Cefuroxime	250 mg	Film-coated tablet	Oral use
Austria	Krka d.d., Novo mesto		Cefuroxim Krka 500 mg Filmtabletten	Cefuroxime	500 mg	Film-coated tablet	Oral use
Bulgaria	Krka d.d., Novo mesto		Furocef 250 mg film-coated tablets	Cefuroxime	250 mg	Film-coated tablet	Oral use
Bulgaria	Krka d.d., Novo mesto		Furocef 500 mg film-coated tablets	Cefuroxime	500 mg	Film-coated tablet	Oral use
Croatia	Krka — farma d.o.o.		Furocef 250 mg film-coated tablets	Cefuroxime	250 mg	Film-coated tablet	Oral use
Croatia	Krka — farma d.o.o.		Furocef 500 mg film-coated tablets	Cefuroxime	500 mg	Film-coated tablet	Oral use
Czech Republic	Krka d.d., Novo mesto		Ricefan 250 mg	Cefuroxime	250 mg	Film-coated tablet	Oral use
Czech Republic	Krka d.d., Novo mesto		Ricefan 500 mg	Cefuroxime	500 mg	Film-coated tablet	Oral use
Estonia	Krka d.d., Novo mesto		FUROCEF	Cefuroxime	250 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Estonia	Krka d.d., Novo mesto		FUROCEF	Cefuroxime	500 mg	Film-coated tablet	Oral use
France	Krka d.d., Novo mesto		CEFUROXIME KRKA 250 mg, comprimé pelliculé	Cefuroxime	250 mg	Film-coated tablet	Oral use
France	Krka d.d., Novo mesto		CEFUROXIME KRKA 500 mg, comprimé pelliculé	Cefuroxime	500 mg	Film-coated tablet	Oral use
Germany	Alkem Pharma GmbH		Cefuroxim Alkem 250 mg Filmtabletten	Cefuroxime axetil	250 mg	Film-coated tablet	Oral use
Germany	Alkem Pharma GmbH		Cefuroxim Alkem 500 mg Filmtabletten	Cefuroxime axetil	500 mg	Film-coated tablet	Oral use
Hungary	Krka d.d., Novo mesto		Furocef Krka 250 mg tablets	Cefuroxime	250 mg	Tablet	Oral use
Hungary	Krka d.d., Novo mesto		Furocef Krka 500 mg tablets	Cefuroxime	500 mg	Tablet	Oral use
Latvia	Krka d.d., Novo mesto		Ricefan 250 mg film-coated tablets	Cefuroxime	250 mg	Film-coated tablet	Oral use
Latvia	Krka d.d., Novo mesto		Ricefan 500 mg film-coated tablets	Cefuroxime	500 mg	Film-coated tablet	Oral use
Lithuania	Krka d.d., Novo mesto		Ricefan	Cefuroxime	250 mg	Film-coated tablet	Oral use
Lithuania	Krka d.d., Novo mesto		Ricefan	Cefuroxime	500 mg	Film-coated tablet	Oral use
Lithuania		SIA Ingen Pharma	Cefuroxime Ingen Pharma	Cefuroxime	250 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Lithuania		SIA Ingen Pharma	Cefuroxime Ingen Pharma	Cefuroxime	500 mg	Film-coated tablet	Oral use
Poland	Krka d.d., Novo mesto		Furocef	Cefuroxime	250 mg	Film-coated tablet	Oral use
Poland	Krka d.d., Novo mesto		Furocef	Cefuroxime	500 mg	Film-coated tablet	Oral use
Portugal	Krka d.d., Novo mesto		Cefuroxima Krka	Cefuroxime axetil	250 mg	Film-coated tablet	Oral use
Portugal	Krka d.d., Novo mesto		Cefuroxima Krka	Cefuroxime axetil	500 mg	Film-coated tablet	Oral use
Romania	Krka d.d., Novo mesto		CEFUROXIME KRKA 250 mg, comprimate	Cefuroxime	250 mg	Film-coated tablet	Oral use
Romania	Krka d.d., Novo mesto		CEFUROXIME KRKA 500 mg, comprimate	Cefuroxime	500 mg	Film-coated tablet	Oral use
Slovak Republic	Krka d.d., Novo mesto		Furocef 250 mg filmom obalené tablety	Cefuroxime	250 mg	Film-coated tablet	Oral use
Slovak Republic	Krka d.d., Novo mesto		Furocef 500 mg filmom obalené tablety	Cefuroxime	500 mg	Film-coated tablet	Oral use
Slovenia	Krka d.d., Novo mesto		Ricefan	Cefuroxime	250 mg	Film-coated tablet	Oral use
Slovenia	Krka d.d., Novo mesto		Ricefan	Cefuroxime	500 mg	Film-coated tablet	Oral use
Spain	Alkem Pharma GmbH		Cefuroxima 500 mg comprimidos recubiertos con película	Cefuroxime axetil	500 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Spain	Alkem Pharma GmbH		Cefuroxima Alkem 250 mg comprimidos recubiertos con película	Cefuroxime axetil	250 mg	Film-coated tablet	Oral use
Spain	Krka d.d., Novo mesto		Cefuroxima KRKA 250 mg comprimidos recubiertos con película	Cefuroxime	250 mg	Film-coated tablet	Oral use
Spain	Krka d.d., Novo mesto		Cefuroxima KRKA 500 mg comprimidos recubiertos con película	Cefuroxime	500 mg	Film-coated tablet	Oral use
United Kingdom	Alkem Pharma GmbH		Cefuroxime 250 mg film-coated tablets	Cefuroxime axetil	250 mg	Film-coated tablet	Oral use
United Kingdom	Alkem Pharma GmbH		Cefuroxime 500 mg film-coated tablets	Cefuroxime axetil	500 mg	Film-coated tablet	Oral use

Annex IB: Products for which the marketing authorisations are recommended for suspension and marketing authorisation applications which do not satisfy the criteria for authorisation

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Czech Republic	Alkem Pharma GmbH		Riluzole Alkem 50 mg potahované tablety	Riluzole	50 mg	Film-coated tablet	Oral use
Denmark		Orion Corporation	Ibuprofen Orion	Ibuprofen	200 mg	Film-coated tablet	Oral use
Denmark		Orion Corporation	Ibuprofen Orion	Ibuprofen	400 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Denmark		Orion Corporation	Ibuprofen Orion	Ibuprofen	600 mg	Film-coated tablet	Oral use
Germany	Alkem Pharma GmbH		Riluzol Alkem 50 mg Filmtabletten	Riluzole	50 mg	Film-coated tablet	Oral use
Spain	Alkem Pharma GmbH		Riluzole 50 mg comprimidos recubiertos con película EFG	Riluzole	50 mg	Film-coated tablet	Oral use
Sweden		Orion Corporation	Ibuprofen Orion	Ibuprofen	200 mg	Film-coated tablet	Oral use
Sweden		Orion Corporation	Ibuprofen Orion	Ibuprofen	400 mg	Film-coated tablet	Oral use
Sweden		Orion Corporation	Ibuprofen Orion	Ibuprofen	600 mg	Film-coated tablet	Oral use
United Kingdom	Alkem Pharma GmbH		Riluzole alkem 50 mg film-coated tablets	Riluzole	50 mg	Film-coated tablet	Oral use

ANNEX III

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

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Austria	Janssen-Cilag Pharma GmbH, 1020 Vienna, Vorgartenstraße 206B Austria	Durogesic	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Austria	Janssen-Cilag Pharma GmbH, 1020 Vienna, Vorgartenstraße 206B Austria	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Austria	Janssen-Cilag Pharma GmbH, 1020 Vienna, Vorgartenstraße 206B Austria	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Austria	Janssen-Cilag Pharma GmbH, 1020 Vienna, Vorgartenstraße 206B Austria	Durogesic	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Austria	Janssen-Cilag Pharma GmbH, 1020 Vienna, Vorgartenstraße 206B Austria	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Belgium	Janssen-Cilag N.V. Antwerpseweg 15-17 B-2340 Beerse Belgium	Durogesic	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Belgium	Janssen-Cilag N.V. Antwerpseweg 15-17 B-2340 Beerse Belgium	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Belgium	Janssen-Cilag N.V. Antwerpseweg 15-17 B-2340 Beerse Belgium	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Belgium	Janssen-Cilag N.V. Antwerpseweg 15-17 B-2340 Beerse Belgium	Durogesic	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Belgium	Janssen-Cilag N.V. Antwerpseweg 15-17 B-2340 Beerse Belgium	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Croatia	Johnson & Johnson S.E. d.o.o. Oreškovićeva 6H, 10010 Zagreb, Croatia	Durogesic	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Croatia	Johnson & Johnson S.E. d.o.o. Oreškovićeva 6H, 10010 Zagreb, Croatia	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Croatia	Johnson & Johnson S.E. d.o.o. Oreškovićeva 6H, 10010 Zagreb, Croatia	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Croatia	Johnson & Johnson S.E. d.o.o. Oreškovićeva 6H, 10010 Zagreb, Croatia	Durogesic	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Croatia	Johnson & Johnson S.E. d.o.o. Oreškovićeva 6H, 10010 Zagreb, Croatia	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Cyprus	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse Belgium	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Cyprus	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse Belgium	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Cyprus	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse Belgium	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Czech Republic	Janssen-Cilag s.r.o., Karla Engliše 3201/6, Prague 5, 150 00 Czech Republic	Durogesic 12 mcg/h	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Czech Republic	Janssen-Cilag s.r.o., Karla Engliše 3201/6, Prague 5, 150 00 Czech Republic	Durogesic 25 mcg/h	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Czech Republic	Janssen-Cilag s.r.o., Karla Engliše 3201/6, Prague 5, 150 00 Czech Republic	Durogesic 50 mcg/h	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Czech Republic	Janssen-Cilag s.r.o., Karla Engliše 3201/6, Prague 5, 150 00 Czech Republic	Durogesic 75 mcg/h	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Czech Republic	Janssen-Cilag s.r.o., Karla Engliše 3201/6, Prague 5, 150 00 Czech Republic	Durogesic 100 mcg/h	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Denmark	Janssen Cilag A/S Bregnerødvej 133 3460 Birkerød Denmark	Durogesic	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Denmark	Janssen Cilag A/S Bregnerødvej 133 3460 Birkerød Denmark	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Denmark	Janssen Cilag A/S Bregnerødvej 133 3460 Birkerød Denmark	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Denmark	Janssen Cilag A/S Bregnerødvej 133 3460 Birkerød Denmark	Durogesic	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Denmark	Janssen Cilag A/S Bregnerødvej 133 3460 Birkerød Denmark	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Finland	Janssen-Cilag Oy, Vaisalantie 2, 02130 Espoo Finland	Durogesic	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Finland	Janssen-Cilag Oy, Vaisalantie 2, 02130 Espoo Finland	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Finland	Janssen-Cilag Oy, Vaisalantie 2, 02130 Espoo Finland	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Finland	Janssen-Cilag Oy, Vaisalantie 2, 02130 Espoo Finland	Durogesic	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Finland	Janssen-Cilag Oy, Vaisalantie 2, 02130 Espoo Finland	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
France	JANSSEN-CILAG 1, rue Camille Desmoulins TSA 91003 92787 ISSY-LES-MOULINEAUX Cedex 9 France	Durogesic 12 microgrammes/heure, dispositif transdermique	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
France	JANSSEN-CILAG 1, rue Camille Desmoulins TSA 91003 92787 ISSY-LES-MOULINEAUX Cedex 9 France	Durogesic 25 microgrammes/heure, dispositif transdermique	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
France	JANSSEN-CILAG 1, rue Camille Desmoulins TSA 91003 92787 ISSY-LES-MOULINEAUX Cedex 9 France	Durogesic 50 microgrammes/heure, dispositif transdermique	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
France	JANSSEN-CILAG 1, rue Camille Desmoulins TSA 91003 92787 ISSY-LES-MOULINEAUX Cedex 9 France	Durogesic 75 microgrammes/heure, dispositif transdermique	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
France	JANSSEN-CILAG 1, rue Camille Desmoulins TSA 91003 92787 ISSY-LES-MOULINEAUX Cedex 9 France	Durogesic 100 microgrammes/heure, dispositif transdermique	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Germany	JANSSEN-CILAG GmbH Johnson & Johnson Platz 1 41470 Neuss, Germany	Durogesic SMAT	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Germany	JANSSEN-CILAG GmbH Johnson & Johnson Platz 1 41470 Neuss, Germany	Durogesic SMAT	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Germany	JANSSEN-CILAG GmbH Johnson & Johnson Platz 1 41470 Neuss, Germany	Durogesic SMAT	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Germany	JANSSEN-CILAG GmbH Johnson & Johnson Platz 1 41470 Neuss, Germany	Durogesic SMAT	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Germany	JANSSEN-CILAG GmbH Johnson & Johnson Platz 1 41470 Neuss, Germany	Durogesic SMAT	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave., 151 21, Pefki, Greece	Durogesic	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave., 151 21, Pefki, Greece	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave., 151 21, Pefki, Greece	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave., 151 21, Pefki, Greece	Durogesic	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave., 151 21, Pefki, Greece	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Hungary	Janssen-Cilag Kft. 1123 Budapest, Nagyenyed utca 8-14 Magyarország Hungary	Durogesic 12 mikrogramm/óra transzdermális tapasz	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Hungary	Janssen-Cilag Kft. 1123 Budapest, Nagyenyed utca 8-14 Magyarország Hungary	Durogesic 25 mikrogramm/óra transzdermális tapasz	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Hungary	Janssen-Cilag Kft. 1123 Budapest, Nagyenyed utca 8-14 Magyarország Hungary	Durogesic 50 mikrogramm/óra transzdermális tapasz	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Hungary	Janssen-Cilag Kft. 1123 Budapest, Nagyenyed utca 8-14 Magyarország Hungary	Durogesic 75 mikrogramm/óra transzdermális tapasz	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Hungary	Janssen-Cilag Kft. 1123 Budapest, Nagyenyed utca 8-14 Magyarország Hungary	Durogesic 100 mikrogramm/óra transzdermális tapasz	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Iceland	Janssen-Cilag AB Box 7073 192 07 Sollentuna Sweden	Durogesic	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Iceland	Janssen-Cilag AB Box 7073 192 07 Sollentuna Sweden	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Iceland	Janssen-Cilag AB Box 7073 192 07 Sollentuna Sweden	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Iceland	Janssen-Cilag AB Box 7073 192 07 Sollentuna Sweden	Durogesic	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Iceland	Janssen-Cilag AB Box 7073 192 07 Sollentuna Sweden	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Ireland	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Durogesic DTrans	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Ireland	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Durogesic DTrans	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Ireland	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Durogesic DTrans	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Ireland	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Durogesic DTrans	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Ireland	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Durogesic DTrans	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Italy	JANSSEN-CILAG SpA Via M. Buonarroti, 23 20093 COLOGNO MONZESE (MI), Italy	Durogesic	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Italy	JANSSEN-CILAG SpA Via M. Buonarroti, 23 20093 COLOGNO MONZESE (MI), Italy	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Italy	JANSSEN-CILAG SpA Via M. Buonarroti, 23 20093 COLOGNO MONZESE (MI), Italy	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Italy	JANSSEN-CILAG SpA Via M. Buonarroti, 23 20093 COLOGNO MONZESE (MI), Italy	Durogesic	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Italy	JANSSEN-CILAG SpA Via M. Buonarroti, 23 20093 COLOGNO MONZESE (MI), Italy	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Luxembourg	Janssen-Cilag N.V. Antwerpseweg 15-17 B-2340 Beerse Belgium	Durogesic	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Luxembourg	Janssen-Cilag N.V. Antwerpseweg 15-17 B-2340 Beerse Belgium	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Luxembourg	Janssen-Cilag N.V. Antwerpseweg 15-17 B-2340 Beerse Belgium	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Luxembourg	Janssen-Cilag N.V. Antwerpseweg 15-17 B-2340 Beerse Belgium	Durogesic	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Luxembourg	Janssen-Cilag N.V. Antwerpseweg 15-17 B-2340 Beerse Belgium	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Malta	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse Belgium	Durogesic DTrans	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Malta	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse Belgium	Durogesic DTrans	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Malta	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse Belgium	Durogesic DTrans	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Malta	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse Belgium	Durogesic DTrans	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Malta	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse Belgium	Durogesic DTrans	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 5026 RH Tilburg PO Box 90240 5000 LT Tilburg Netherlands	Durogesic 12 µg/uur	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 5026 RH Tilburg PO Box 90240 5000 LT Tilburg Netherlands	Durogesic 25 µg/uur	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 5026 RH Tilburg PO Box 90240 5000 LT Tilburg Netherlands	Durogesic 50 µg/uur	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 5026 RH Tilburg PO Box 90240 5000 LT Tilburg Netherlands	Durogesic 75 µg/uur	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 5026 RH Tilburg PO Box 90240 5000 LT Tilburg Netherlands	Durogesic 100 µg/uur	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Norway	Janssen-Cilag AS Drammensveien 288 NO-0283 Oslo Norway	Durogesic	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Norway	Janssen-Cilag AS Drammensveien 288 NO-0283 Oslo Norway	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Norway	Janssen-Cilag AS Drammensveien 288 NO-0283 Oslo Norway	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Norway	Janssen-Cilag AS Drammensveien 288 NO-0283 Oslo Norway	Durogesic	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Norway	Janssen-Cilag AS Drammensveien 288 NO-0283 Oslo Norway	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Poland	Janssen-Cilag International NV Turnhoutseweg 30 B-2340 Beerse Belgium	Durogesic	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Poland	Janssen-Cilag International NV Turnhoutseweg 30 B-2340 Beerse Belgium	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Poland	Janssen-Cilag International NV Turnhoutseweg 30 B-2340 Beerse Belgium	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Poland	Janssen-Cilag International NV Turnhoutseweg 30 B-2340 Beerse Belgium	Durogesic	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Poland	Janssen-Cilag International NV Turnhoutseweg 30 B-2340 Beerse Belgium	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A Queluz de Baixo 2734-503 Barcarena Portugal	Durogesic	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A Queluz de Baixo 2734-503 Barcarena Portugal	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A Queluz de Baixo 2734-503 Barcarena Portugal	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A Queluz de Baixo 2734-503 Barcarena Portugal	Durogesic	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A Queluz de Baixo 2734-503 Barcarena Portugal	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Slovenia	Johnson & Johnson d.o.o. Šmartinska cesta 53, 1000 Ljubljana Slovenia	Durogesic	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Slovenia	Johnson & Johnson d.o.o. Šmartinska cesta 53, 1000 Ljubljana Slovenia	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Slovenia	Johnson & Johnson d.o.o. Šmartinska cesta 53, 1000 Ljubljana Slovenia	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Slovenia	Johnson & Johnson d.o.o. Šmartinska cesta 53, 1000 Ljubljana Slovenia	Durogesic	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Slovenia	Johnson & Johnson d.o.o. Šmartinska cesta 53, 1000 Ljubljana Slovenia	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Spain	JANSSEN-CILAG, S.A. Paseo de Las Doce Estrellas, 5-7 28042, Madrid Spain	Durogesic Matrix	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Spain	JANSSEN-CILAG, S.A. Paseo de Las Doce Estrellas, 5-7 28042, Madrid Spain	Durogesic Matrix	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Spain	JANSSEN-CILAG, S.A. Paseo de Las Doce Estrellas, 5-7 28042, Madrid Spain	Durogesic Matrix	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Spain	JANSSEN-CILAG, S.A. Paseo de Las Doce Estrellas, 5-7 28042, Madrid Spain	Durogesic Matrix	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Spain	JANSSEN-CILAG, S.A. Paseo de Las Doce Estrellas, 5-7 28042, Madrid Spain	Durogesic Matrix	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour
Sweden	Janssen-Cilag AB Box 7073 192 07 Sollentuna Sweden	Durogesic	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
Sweden	Janssen-Cilag AB Box 7073 192 07 Sollentuna Sweden	Durogesic	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
Sweden	Janssen-Cilag AB Box 7073 192 07 Sollentuna Sweden	Durogesic	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
Sweden	Janssen-Cilag AB Box 7073 192 07 Sollentuna Sweden	Durogesic	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
Sweden	Janssen-Cilag AB Box 7073 192 07 Sollentuna Sweden	Durogesic	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour

Member State EU/ EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
United Kingdom	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Durogesic DTrans	12 µg/h	Transdermal patch	Transdermal use	2,1 mg/5,25 cm^2 which release 12,5 µg fentanyl per hour
United Kingdom	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Durogesic DTrans	25 µg/h	Transdermal patch	Transdermal use	4,2 mg/10,5 cm^2 which release 25 µg fentanyl per hour
United Kingdom	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Durogesic DTrans	50 µg/h	Transdermal patch	Transdermal use	8,4 mg/21 cm^2 which release 50 µg fentanyl per hour
United Kingdom	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Durogesic DTrans	75 µg/h	Transdermal patch	Transdermal use	12,6 mg/31,5 cm^2 which release 75 µg fentanyl per hour
United Kingdom	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Durogesic DTrans	100 µg/h	Transdermal patch	Transdermal use	16,8 mg/42 cm^2 which release 100 µg fentanyl per hour

ANNEX IV

List of nationally authorised medicinal products and marketing authorisation applications

Annex IA: Medicinal products recommended for maintenance and marketing authorisation applications for which bioequivalence vis-à-vis the EU reference medicinal product has been established

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Austria		Lupin (Europe) Ltd	Abacavir/Lamivudin Aristo 600 mg/300 mg Filmtabletten	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Austria		Lupin (Europe) Ltd	Abacavir/Lamivudin Sandoz 600 mg/300 mg — Filmtabletten	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Belgium		Lupin (Europe) Ltd	Abacavir/Lamivudin Sandoz	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Belgium		Mylan bvba	Abacavir/Lamivudin Mylan	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Bulgaria	Sandoz d.d.		Abacavir/Lamivudin Sandoz	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Croatia		Lupin (Europe) Ltd	Abakavir/Lamivudin Sandoz 600 mg/300 mg filmom obložene tablete	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Cyprus		Lupin (Europe) Ltd	Abacavir/Lamivudine Sandoz	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Denmark		Lupin (Europe) Ltd	Abacavir/Lamivudine Sandoz	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Denmark		Mylan AB	Abacavir/Lamivudine Mylan	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Estonia		Lupin (Europe) Ltd	ABACAVIR/LAMIVUDINE SANDOZ	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Finland		Lupin (Europe) Ltd	Abacavir/Lamivudine Sandoz	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Finland		Mylan AB	Abacavir/Lamivudine Mylan	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
France		Venipharm	BAMIVENI	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
France		Venipharm	BAMIVUDINE	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
France		Venipharm	VIRAMUDINE	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Germany		Lupin (Europe) Ltd	Abacavir/Lamivudin 600 mg/ 300 mg Filmtabletten	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Germany		Lupin (Europe) Ltd	Abacavir/Lamivudine Hormosan 600 mg/300 mg Filmtabletten	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Germany		Lupin (Europe) Ltd	Abacavir/Lamivudin HEXAL 600 mg/300 mg Filmtabletten	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Germany		Lupin (Europe) Ltd	Abacavir/Lamivudin Aristo 600 mg/300 mg Filmtabletten	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Germany		Lupin (Europe) Ltd	Abacavir/Lamivudin Klinge 600 mg/300 mg Filmtabletten	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Ireland		Generics (UK) Limited	Abacavir/Lamivudine	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Ireland		Lupin (Europe) Ltd	Abacavir/Lamivudine Rowex	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Italy		Lupin (Europe) Ltd	ABACAVIR E LAMIVUDINA LUPIN	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Italy		Lupin (Europe) Ltd	ABACAVIR E LAMIVUDINA SANDOZ	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Italy		Lupin (Europe) Ltd	ABACAVIR E LAMIVUDINA MYLAN	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Italy		Lupin (Europe) Ltd	ABACAVIR E LAMIVUDINA ARISTO	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Lithuania		Lupin (Europe) Ltd	Abacavir/Lamivudine Sandoz 600 mg/300 mg plėvele dengtos tabletės	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Norway		Mylan AB	Abacavir/Lamivudin Mylan	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Poland		Lupin (Europe) Ltd	Abacavir+Lamivudine Sandoz	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Poland		Lupin (Europe) Ltd	Abacavir + Lamivudine Mylan	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Portugal		Lupin (Europe) Ltd	Abacavir + Lamivudina Lupin	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Portugal		Lupin (Europe) Ltd	Abacavir + Lamivudina Sandoz	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Portugal		Mylan, Lda.	Abacavir + Lamivudina Mylan	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Romania		Lupin (Europe) Ltd	Abacavir/lamivudină Sandoz 600 mg/300 mg, film-coated tablets	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Slovenia		Lupin (Europe) Ltd	Abakavir/lamivudin Sandoz 600 mg/300 mg filmsko obložene tablete	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Spain		Lupin (Europe) Ltd	Abacavir/Lamivudina Amneal 600 mg/300 mg comprimidos recubiertos con película EFG	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Spain		Lupin (Europe) Ltd	Abacavir/Lamivudina Aristo 600 mg/300 mg comprimidos recubiertos con película EFG	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Spain		Sandoz B.V.	Abacavir/Lamivudina Sandoz 600 mg/300 mg comprimidos recubiertos con película EFG	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L.		Abacavir/Lamivudina Mylan 600 mg/300 mg comprimidos recubiertos con película EFG	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Sweden		Lupin (Europe) Ltd	Abacavir/Lamivudine Sandoz	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Sweden		Mylan AB	Abacavir/Lamivudine Mylan	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
The Netherlands		Lupin (Europe) Ltd	Abacavir/Lamivudine Aristo	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
The Netherlands		Lupin (Europe) Ltd	Abacavir/Lamivudine Lupin	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
The Netherlands		Lupin (Europe) Ltd	Abacavir/Lamivudine Lupin	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
United Kingdom		Aristo Pharma GmbH	Abacavir/lamivudine 600 mg/ 300 mg film-coated tablets	abacavir/lamivudine	600 mg/300 mg	Tablet	Oral use
United Kingdom		Lupin (Europe) Ltd	Abacavir/lamivudine 600 mg/ 300 mg film-coated tablets	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
United Kingdom		Lupin (Europe) Ltd	Abacavir/lamivudine 600 mg/ 300 mg film-coated tablets	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
United Kingdom		Generics (UK) Limited	Abacavir/lamivudine 600 mg/ 300 mg film-coated tablets	abacavir/lamivudine	600 mg/300 mg	Film-coated tablet	Oral use

Annex IB: Products for which the marketing authorisations are recommended for suspension and marketing authorisation applications which do not satisfy the criteria for authorisation

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Belgium		Sandoz NV	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
Belgium		Sandoz NV	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
Belgium		Sandoz NV	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Belgium		Teva Pharma Belgium NV	Erlotinib Ratiopharm	erlotinib	25 mg	Film-coated tablet	Oral use
Belgium		Teva Pharma Belgium NV	Erlotinib Ratiopharm	erlotinib	100 mg	Film-coated tablet	Oral use
Belgium		Teva Pharma Belgium NV	Erlotinib Ratiopharm	erlotinib	150 mg	Film-coated tablet	Oral use
Belgium		Accord Healthcare Ltd	Saquinavir Accord	saquinavir	500 mg	Film-coated tablet	Oral use
Belgium	Teva Pharma Belgium NV		Atovaquone/Proguanil Teva	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
Belgium	Teva Pharma Belgium NV		Atovaquone/Proguanil Teva	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Belgium	Sandoz NV		Malaprotec	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
Belgium	Sandoz NV		Malaprotec	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Belgium	Sandoz NV		Saquinavir Sandoz	saquinavir	500 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Bulgaria		Teva B.V.	Erlotinib Teva Pharma B.V	erlotinib	100 mg	Film-coated tablet	Oral use
Bulgaria		Teva B.V.	Erlotinib Teva Pharma B.V	erlotinib	150 mg	Film-coated tablet	Oral use
Bulgaria		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
Bulgaria		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Bulgaria		Accord Healthcare Limited	Saquinavir Accord	saquinavir	500 mg	Film-coated tablet	Oral use
Croatia		Sandoz B.V.	Erlotinib Sandoz 25 mg filmom obložene tablete	erlotinib	25 mg	Film-coated tablet	Oral use
Croatia		Sandoz B.V.	Erlotinib Sandoz 100 mg filmom obložene tablete	erlotinib	100 mg	Film-coated tablet	Oral use
Croatia		Sandoz B.V.	Erlotinib Sandoz 150 mg filmom obložene tablete	erlotinib	150 mg	Film-coated tablet	Oral use
Croatia		Teva B.V.	Erlotinib Pliva Hrvatska 25 mg filmom obložene tablete	erlotinib	25 mg	Film-coated tablet	Oral use
Croatia		Teva B.V.	Erlotinib Pliva Hrvatska 100 mg filmom obložene tablete	erlotinib	100 mg	Film-coated tablet	Oral use
Croatia		Teva B.V.	Erlotinib Pliva Hrvatska 150 mg filmom obložene tablete	erlotinib	150 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Croatia		Edicta Pharm d.o.o.	Edinib 25 mg filmom obložene tablete	erlotinib	25 mg	Film-coated tablet	Oral use
Croatia		Edicta Pharm d.o.o.	Edinib 100 mg filmom obložene tablete	erlotinib	100 mg	Film-coated tablet	Oral use
Croatia		Edicta Pharm d.o.o.	Edinib 150 mg filmom obložene tablete	erlotinib	150 mg	Film-coated tablet	Oral use
Cyprus		Sandoz B.V.	Erlotinib Hydrochloride Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Cyprus		Accord Healthcare Ltd	Saquinavir Accord	saquinavir	500 mg	Film-coated tablet	Oral use
Czech Republic		Sandoz B.V.	Erlotinib Sandoz 25 mg	erlotinib	25 mg	Film-coated tablet	Oral use
Czech Republic		Sandoz B.V.	Erlotinib Sandoz 100 mg	erlotinib	100 mg	Film-coated tablet	Oral use
Czech Republic		Sandoz B.V.	Erlotinib Sandoz 150 mg	erlotinib	150 mg	Film-coated tablet	Oral use
Czech Republic		Vipharm S.A.	Erlotinib Vipharm 25 mg potahovane tablety	erlotinib	25 mg	Film-coated tablet	Oral use
Czech Republic		Vipharm S.A.	Erlotinib Vipharm 100 mg potahovane tablety	erlotinib	100 mg	Film-coated tablet	Oral use
Czech Republic		Vipharm S.A.	Erlotinib Vipharm 150 mg potahovane tablety	erlotinib	150 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Denmark		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
Denmark		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
Denmark		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Denmark	Orifarm Generics A/S		Atovaquone/Proguanil Orifarm	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Denmark	ratiopharm GmBH		Atovaquone/Proguanil ratiopharm	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Denmark	Sandoz A/S		Horisto	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
Denmark	Sandoz A/S		Horisto	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Denmark	Mylan AB		Eletriptan Mylan	eletriptan	40 mg	Film-coated tablet	Oral use
Estonia		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
Estonia		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
Estonia		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Estonia		Teva B.V.	ERLOTINIB TEVA GENERICS	erlotinib	100 mg	Film-coated tablet	Oral use
Estonia		Teva B.V.	ERLOTINIB TEVA GENERICS	erlotinib	150 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Finland	ratiopharm GmbH		Atovaquone/Proguanil ratiopharm	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Finland	Sandoz A/S		Rumbabor	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
Finland	Sandoz A/S		Rumbabor	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Finland	Mylan AB		Eletriptan Mylan	eletriptan	40 mg	Film-coated tablet	Oral use
France		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
France		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
France		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
France		Teva B.V.	Erlotinib Teva Pharma	erlotinib	25 mg	Film-coated tablet	Oral use
France		Teva B.V.	Erlotinib Teva Pharma	erlotinib	100 mg	Film-coated tablet	Oral use
France		Teva B.V.	Erlotinib Teva Pharma	erlotinib	150 mg	Film-coated tablet	Oral use
France		Sandoz B.V.	SAQUINAVIR SANDOZ	saquinavir	500 mg	Film-coated tablet	Oral use
France		Medipha Sante	AMOXICILLINE MEDIPHA 1 g	amoxicillin	1 g	Orodispersible tablet	Oral use
France	Medipha Sante		Amoxicilline Authou	amoxicillin	1 g	Orodispersible tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
France	Sandoz		Atovaquone/Proguanil Sandoz ENFANTS	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
France	Sandoz		Atovaquone/Proguanil Sandoz	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
France	Teva Sante		Atovaquone/Proguanil Teva ENFANTS	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
France	Teva Sante		Atovaquone/Proguanil Teva	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
France	Venipharm		EBACHOI	ebastine	10 mg	Orodispersible tablet	Oral use
France	Venipharm		EBARREN	ebastine	10 mg	Film-coated tablet	Oral use
France	Biogaran		EBASTINE BIOGARAN	ebastine	10 mg	Film-coated tablet	Oral use
France	Biogaran		EBASTINE BIOGARAN	ebastine	10 mg	Orodispersible tablet	Oral use
France	Mylan SAS		EBASTINE MYLAN	ebastine	10 mg	Orodispersible tablet	Oral use
France	Mylan SAS		EBASTINE MYLAN	ebastine	10 mg	Film-coated tablet	Oral use
France	Sanofi Aventis France		EBASTINE ZENTIVA	ebastine	10 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
France	Sanofi Aventis France		EBASTINE ZENTIVA	ebastine	10 mg	Orodispersible tablet	Oral use
France	Venipharm		EBONDE	ebastine	10 mg	Film-coated tablet	Oral use
France	Venipharm		EBONTAN	ebastine	10 mg	Orodispersible tablet	Oral use
France	Venipharm		EBOUDA	ebastine	10 mg	Film-coated tablet	Oral use
France	Mylan SAS		Eletriptan Mylan	eletriptan	20 mg	Film-coated tablet	Oral use
France	Mylan SAS		Eletriptan Mylan	eletriptan	40 mg	Film-coated tablet	Oral use
France	Medipha Sante		Tramadol/Paracétamol Nialex	tramadol/paracetamol	37,5 mg/325 mg	Film-coated tablet	Oral use
France	Zydus France		Tramadol/Paracétamol Zydus France	tramadol/paracetamol	37,5 mg/325 mg	Film-coated tablet	Oral use
Germany		Pharma Resources GmbH	Etoricoxib PhaRes 30 mg Filmtabletten	etoricoxib	30 mg	Film-coated tablet	Oral use
Germany		Pharma Resources GmbH	Etoricoxib PhaRes 60 mg Filmtabletten	etoricoxib	60 mg	Film-coated tablet	Oral use
Germany		Pharma Resources GmbH	Etoricoxib PhaRes 90 mg Filmtabletten	etoricoxib	90 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Germany		Pharma Resources GmbH	Etoricoxib PhaRes 120 mg Filmtabletten	etoricoxib	120 mg	Film-coated tablet	Oral use
Germany		Bristol Laboratories Ltd.	Celecoxib axcount 100 mg Hartkapseln	celecoxib	100 mg	Capsule, hard	Oral use
Germany		Bristol Laboratories Ltd.	Celecoxib axcount 200 mg Hartkapseln	celecoxib	200 mg	Capsule, hard	Oral use
Germany		Micro Labs GmbH	Amoxicillin Micro Labs 250 mg	amoxicillin	250 mg	Film-coated tablet	Oral use
Germany		Micro Labs GmbH	Amoxicillin Micro Labs 500 mg	amoxicillin	500 mg	Film-coated tablet	Oral use
Germany		Micro Labs GmbH	Amoxicillin Micro Labs 750 mg	amoxicillin	750 mg	Film-coated tablet	Oral use
Germany		Micro Labs GmbH	Amoxicillin Micro Labs 1 000 mg	amoxicillin	1 000 mg	Film-coated tablet	Oral use
Germany		Micro Labs GmbH	Rasagilin Micro Labs 1 mg Tabletten	rasagiline	1 mg	Film-coated tablet	Oral use
Germany		Lupin (Europe) Ltd	Duloxetin-Hormosan 60 mg magensaftresistente Hartkapseln	duloxetine	60 mg	Capsule, hard	Oral use
Germany		Lupin (Europe) Ltd	Duloxetin-Hormosan 40 mg magensaftresistente Hartkapseln	duloxetine	40 mg	Capsule, hard	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Germany		Lupin (Europe) Ltd	Duloxetin-Hormosan 30 mg magensaftresistente Hartkapseln	duloxetine	30 mg	Capsule, hard	Oral use
Germany		Lupin (Europe) Ltd	Duloxetin-Hormosan 20 mg magensaftresistente Hartkapseln	duloxetine	20 mg	Capsule, hard	Oral use
Germany		Micro Labs GmbH	Irbesartan/Hydrochlorothiazide Micro Labs 150 mg/ 12,5 mg Filmtabletten	irbesartan/hydrochlorothiazide	150 mg/12,5 mg	Film-coated tablet	Oral use
Germany		Micro Labs GmbH	Irbesartan/Hydrochlorothiazide Micro Labs 300 mg/ 12,5 mg Filmtabletten	irbesartan/hydrochlorothiazide	300 mg/12,5 mg	Film-coated tablet	Oral use
Germany		Micro Labs GmbH	Irbesartan/Hydrochlorothiazide Micro Labs 300 mg/ 25 mg Filmtabletten	irbesartan/hydrochlorothiazide	300 mg/25 mg	Film-coated tablet	Oral use
Germany		Sandoz B.V.	Erlotinib HEXAL 25 mg Filmtabletten	erlotinib	25 mg	Film-coated tablet	Oral use
Germany		Sandoz B.V.	Erlotinib HEXAL 100 mg Filmtabletten	erlotinib	100 mg	Film-coated tablet	Oral use
Germany		Sandoz B.V.	Erlotinib HEXAL 150 mg Filmtabletten	erlotinib	150 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Germany		Sandoz B.V.	Erlotinib — 1 A Pharma 25 mg Filmtabletten	erlotinib	25 mg	Film-coated tablet	Oral use
Germany		Sandoz B.V.	Erlotinib — 1 A Pharma 100 mg Filmtabletten	erlotinib	100 mg	Film-coated tablet	Oral use
Germany		Sandoz B.V.	Erlotinib — 1 A Pharma 150 mg Filmtabletten	erlotinib	150 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 25 mg Filmtabletten	erlotinib	25 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 100 mg Filmtabletten	erlotinib	100 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 150 mg Filmtabletten	erlotinib	150 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 25 mg Filmtabletten	erlotinib	25 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 100 mg Filmtabletten	erlotinib	100 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 150 mg Filmtabletten	erlotinib	150 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 25 mg Filmtabletten	erlotinib	25 mg	Film-coated tablet	Oral use
Germany		Teva B.V.	Erlotinib-ratiopharm 100 mg Filmtabletten	erlotinib	100 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Germany		Teva B.V.	Erlotinib-ratiopharm 150 mg Filmtabletten	erlotinib	150 mg	Film-coated tablet	Oral use
Germany	Hexal Aktiengesellschaft		Saquinavir HEXAL 500 mg Filmtabletten	saquinavir	500 mg	Film-coated tablet	Oral use
Germany	ratiopharm GmbH		Atovaquon/Proguanilhydrochlorid-ratiopharm 62,5 mg/25 mg Filmtabletten	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
Germany	ratiopharm GmbH		Atovaquon/Proguanilhydrochlorid-ratiopharm 250 mg/100 mg Filmtabletten	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Germany	1A Pharma GmbH		Atovaquon/Proguanilhydrochlorid — 1 A Pharma 250 mg/100 mg Filmtabletten	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Germany	1A Pharma GmbH		Atovaquon/Proguanilhydrochlorid — 1 A Pharma 62,5 mg/25 mg Filmtabletten	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
Germany	Hexal Aktiengesellschaft		Malacomp HEXAL	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Germany	Hexal Aktiengesellschaft		Malacomp HEXAL junior	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
Germany	Hormosan Pharma Gesellschaft mit beschränkter Haftung		Pregabalin-Hormosan 25 mg Hartkapseln	pregabalin	25 mg	Capsule, hard	Oral use
Germany	Aristo Pharma GmbH		Eprosartan Aristo 600 mg Filmtabletten	eprosartan	600 mg	Film-coated tablet	Oral use
Germany	Glenmark Arzneimittel GmbH		Celecoxib Glenmark 200 mg Hartkapseln	celecoxib	200 mg	Capsule, hard	Oral use
Germany	Glenmark Arzneimittel GmbH		Celecoxib Glenmark 100 mg Hartkapseln	celecoxib	100 mg	Capsule, hard	Oral use
Greece		Genepharm SA	ERLOTINIB/GENEPHARM	erlotinib	25 mg	Film-coated tablet	Oral use
Greece		Genepharm SA	ERLOTINIB/GENEPHARM	erlotinib	100 mg	Film-coated tablet	Oral use
Greece		Genepharm SA	ERLOTINIB/GENEPHARM	erlotinib	150 mg	Film-coated tablet	Oral use
Hungary		Vipharm S.A.	ERLOTINIB VIPHARM 100 mg filmtabletta	erlotinib	100 mg	Film-coated tablet	Oral use
Hungary		Vipharm S.A.	ERLOTINIB VIPHARM 150 mg filmtabletta	erlotinib	150 mg	Film-coated tablet	Oral use
Hungary		Vipharm S.A.	ERLOTINIB VIPHARM 25 mg filmtabletta	erlotinib	25 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Hungary		Sandoz B.V.	ERLOTINIB Sandoz 25 mg filmtabletta	erlotinib	25 mg	Film-coated tablet	Oral use
Hungary		Sandoz B.V.	ERLOTINIB Sandoz 100 mg filmtabletta	erlotinib	100 mg	Film-coated tablet	Oral use
Hungary		Sandoz B.V.	ERLOTINIB Sandoz 150 mg filmtabletta	erlotinib	150 mg	Film-coated tablet	Oral use
Hungary		Lupin (Europe) Ltd	Pregabalin Merck 25 mg kemény kapszula	pregabalin	25 mg	Capsule, hard	Oral use
Iceland	Lyfis ehf.		Celecoxib LYFIS	celecoxib	100 mg	Capsule, hard	Oral use
Iceland	Lyfis ehf.		Celecoxib LYFIS	celecoxib	200 mg	Capsule, hard	Oral use
Ireland		Sandoz B.V.	Erlotinib Rowex	erlotinib	25 mg	Film-coated tablet	Oral use
Ireland		Sandoz B.V.	Erlotinib Rowex	erlotinib	100 mg	Film-coated tablet	Oral use
Ireland		Sandoz B.V.	Erlotinib Rowex	erlotinib	150 mg	Film-coated tablet	Oral use
Italy		Teva B.V.	ERLOTINIB TEVA	erlotinib	25 mg	Film-coated tablet	Oral use
Italy		Teva B.V.	ERLOTINIB TEVA	erlotinib	100 mg	Film-coated tablet	Oral use
Italy		Teva B.V.	ERLOTINIB TEVA	erlotinib	150 mg	Film-coated tablet	Oral use
Italy		Sandoz B.V.	ERLOTINIB SANDOZ	erlotinib	100 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Italy		Sandoz B.V.	ERLOTINIB SANDOZ	erlotinib	150 mg	Film-coated tablet	Oral use
Italy	Sandoz S.p.A.		ATOVAQUONE E PROGUANILE SANDOZ	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Italy	Sandoz S.p.A.		ATOVAQUONE E PROGUANILE SANDOZ	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
Italy	Sandoz S.p.A.		SAQUINAVIR SANDOZ	saquinavir	500 mg	Film-coated tablet	Oral use
Italy	Mylan S.p.A.		ELETRIPTAN MYLAN	eletriptan	20 mg	Film-coated tablet	Oral use
Italy	Mylan S.p.A.		ELETRIPTAN MYLAN	eletriptan	40 mg	Film-coated tablet	Oral use
Latvia		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss 25 mg film-coated tablets	erlotinib	25 mg	Film-coated tablet	Oral use
Latvia		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss 100 mg film-coated tablets	erlotinib	100 mg	Film-coated tablet	Oral use
Latvia		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss 150 mg film-coated tablets	erlotinib	150 mg	Film-coated tablet	Oral use
Latvia		Sandoz B.V.	Erlotinib Sandoz 25 mg film-coated tablets	erlotinib	25 mg	Film-coated tablet	Oral use
Latvia		Sandoz B.V.	Erlotinib Sandoz 100 mg film-coated tablets	erlotinib	100 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Latvia		Sandoz B.V.	Erlotinib Sandoz 150 mg film-coated tablets	erlotinib	150 mg	Film-coated tablet	Oral use
Latvia		Accord Healthcare Ltd	Saquinavir Accord 500 mg film-coated tablets	saquinavir	500 mg	Film-coated tablet	Oral use
Lithuania		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss	erlotinib	25 mg	Film-coated tablet	Oral use
Lithuania		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss	erlotinib	100 mg	Film-coated tablet	Oral use
Lithuania		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss	erlotinib	150 mg	Film-coated tablet	Oral use
Lithuania		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
Lithuania		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
Lithuania		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Lithuania		Teva B.V.	Erlotinib Teva Generics	erlotinib	150 mg	Film-coated tablet	Oral use
Lithuania		Accord Healthcare Ltd	Saquinavir Accord 500 mg plėvele dengtos tabletės	saquinavir	500 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Luxembourg		Sandoz S.A.	Saquinavir	saquinavir	500 mg	Film-coated tablet	Oral use
Luxembourg		Micro Labs GmbH	Irbesartan/Hydrochlorothiazide Micro Labs 150 mg/ 12,5 mg Filmtabletten	irbesartan/hydrochlorothiazide	150 mg/12,5 mg	Film-coated tablet	Oral use
Luxembourg		Micro Labs GmbH	Irbesartan/Hydrochlorothiazide Micro Labs 300 mg/ 12,5 mg Filmtabletten	irbesartan/hydrochlorothiazide	300 mg/12,5 mg	Film-coated tablet	Oral use
Luxembourg		Micro Labs GmbH	Irbesartan/Hydrochlorothiazide Micro Labs 300 mg/ 25 mg Filmtabletten	irbesartan/hydrochlorothiazide	300 mg/25 mg	Film-coated tablet	Oral use
Luxembourg		Teva B.V.	Erlotinib-ratiopharm 25 mg Filmtabletten	erlotinib	25 mg	Film-coated tablet	Oral use
Luxembourg		Teva B.V.	Erlotinib-ratiopharm 100 mg Filmtabletten	erlotinib	100 mg	Film-coated tablet	Oral use
Luxembourg		Teva B.V.	Erlotinib-ratiopharm 150 mg Filmtabletten	erlotinib	150 mg	Film-coated tablet	Oral use
Luxembourg		Teva B.V.	Erlotinib Ratiopharm	erlotinib	25 mg	Film-coated tablet	Oral use
Luxembourg		Teva B.V.	Erlotinib Ratiopharm	erlotinib	100 mg	Film-coated tablet	Oral use
Luxembourg		Teva B.V.	Erlotinib Ratiopharm	erlotinib	150 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Luxembourg		Micro Labs GmbH	Rasagilin Micro Labs 1 mg Tabletten	rasagiline	1 mg	Film-coated tablet	Oral use
Luxembourg	Sandoz S.A.		Malaprotec	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
Luxembourg	Sandoz S.A.		Malaprotec	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Luxembourg	ratiopharm GmbH		Atovaquon/Proguanilhydrochlorid-ratiopharm 62,5 mg/25 mg Filmtabletten	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
Luxembourg	ratiopharm GmbH		Atovaquon/Proguanilhydrochlorid-ratiopharm 250 mg/100 mg Filmtabletten	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Malta	1A Pharma GmbH		Reprapog	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
Malta	1A Pharma GmbH		Reprapog	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Norway	Mylan AB		Eletriptan Mylan	eletriptan	40 mg	Film-coated tablet	Oral use
Norway	Mylan AB		Eletriptan Mylan	eletriptan	20 mg	Film-coated tablet	Oral use
Norway	Orifarm Generics A/S		Atovaquone/Proguanil Orifarm	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Poland		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
Poland		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
Poland		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Poland		Vipharm S.A.	Erlotinib Vipharm	erlotinib	25 mg	Film-coated tablet	Oral use
Poland		Vipharm S.A.	Erlotinib Vipharm	erlotinib	100 mg	Film-coated tablet	Oral use
Poland		Vipharm S.A.	Erlotinib Vipharm	erlotinib	150 mg	Film-coated tablet	Oral use
Poland	Sandoz GmbH		Saquinavir Sandoz	saquinavir	500 mg	Film-coated tablet	Oral use
Portugal		Brown & Burk UK, Ltd.	Amoxicilina Brown	amoxicillin	250 mg	Film-coated tablet	Oral use
Portugal		Brown & Burk UK, Ltd.	Amoxicilina Brown	amoxicillin	500 mg	Film-coated tablet	Oral use
Portugal		Brown & Burk UK, Ltd.	Amoxicilina Brown	amoxicillin	750 mg	Film-coated tablet	Oral use
Portugal		Brown & Burk UK, Ltd.	Amoxicilina Brown	amoxicillin	1 000 mg	Film-coated tablet	Oral use
Portugal		Teva Pharma — Produtos Farmacêuticos, Lda.	Erlotinib Zidrium	erlotinib	25 mg	Film-coated tablet	Oral use
Portugal		Teva Pharma — Produtos Farmacêuticos, Lda.	Erlotinib Zidrium	erlotinib	100 mg	Film-coated tablet	Oral use
Portugal		Teva Pharma — Produtos Farmacêuticos, Lda.	Erlotinib Zidrium	erlotinib	150 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Portugal		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
Portugal		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
Portugal		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Portugal		Hetero Europe, S.L.	Celecoxib Hetero	Celecoxib	100 mg	Capsule, hard	Oral use
Portugal		Hetero Europe, S.L.	Celecoxib Hetero	Celecoxib	200 mg	Capsule, hard	Oral use
Portugal		Lupin (Europe) Ltd	Pregabalina Merck	Pregabalin	25 mg	Capsule, hard	Oral use
Portugal	Hetero Europe, S.L.		Eprosartan Hetero	eprosartan	600 mg	Film-coated tablet	Oral use
Portugal	Farmoz — Sociedade Técnico Medicinal, S.A.		Saquinavir Farmoz	saquinavir	500 mg	Film-coated tablet	Oral use
Portugal	Lupin (Europe) Ltd		Pregabalina Lupin	pregabalin	25 mg	Capsule, hard	Oral use
Romania		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss 25 mg film-coated tablets	erlotinib	25 mg	Film-coated tablet	Oral use
Romania		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss 100 mg film-coated tablets	erlotinib	100 mg	Film-coated tablet	Oral use
Romania		PharmaSwiss Česká republika s.r.o.	Erlotinib PharmaSwiss 150 mg film-coated tablets	erlotinib	150 mg	Film-coated tablet	Oral use
Romania		Teva B.V.	Erlotinib Teva Pharma 25 mg, film-coated tablets	erlotinib	25 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Romania		Teva B.V.	Erlotinib Teva Pharma 100 mg, film-coated tablets	erlotinib	100 mg	Film-coated tablet	Oral use
Romania		Teva B.V.	Erlotinib Teva Pharma 150 mg, film-coated tablets	erlotinib	150 mg	Film-coated tablet	Oral use
Romania		Sandoz B.V.	Erlotinib Sandoz 25 mg, film-coated tablets	erlotinib	25 mg	Film-coated tablet	Oral use
Romania		Sandoz B.V.	Erlotinib Sandoz 100 mg, film-coated tablets	erlotinib	100 mg	Film-coated tablet	Oral use
Romania		Sandoz B.V.	Erlotinib Sandoz 150 mg, film-coated tablets	erlotinib	150 mg	Film-coated tablet	Oral use
Slovakia		Sandoz B.V.	Erlotinib Sandoz 100 mg, 150 mg	erlotinib	100 mg	Film-coated tablet	Oral use
Slovakia		Sandoz B.V.	Erlotinib Sandoz 100 mg, 150 mg	erlotinib	150 mg	Film-coated tablet	Oral use
Slovakia		Vipharm S.A.	Erlotinib Vipharm 25 mg, 100 mg, 150 mg	erlotinib	25 mg	Film-coated tablet	Oral use
Slovakia		Vipharm S.A.	Erlotinib Vipharm 25 mg, 100 mg, 150 mg	erlotinib	100 mg	Film-coated tablet	Oral use
Slovakia		Vipharm S.A.	Erlotinib Vipharm 25 mg, 100 mg, 150 mg	erlotinib	150 mg	Film-coated tablet	Oral use
Slovakia		PharmaSwiss Česká republika s.r.o.	ERLOTIB 25 mg, 100 mg, 150 mg	erlotinib	25 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Slovakia		PharmaSwiss Česká republika s.r.o.	ERLOTIB 25 mg, 100 mg, 150 mg	erlotinib	100 mg	Film-coated tablet	Oral use
Slovakia		PharmaSwiss Česká republika s.r.o.	ERLOTIB 25 mg, 100 mg, 150 mg	erlotinib	150 mg	Film-coated tablet	Oral use
Slovenia		Sandoz B.V.	Erlotinib Sandoz 25 mg flmsko obložene tablete	erlotinib	25 mg	Film-coated tablet	Oral use
Slovenia		Sandoz B.V.	Erlotinib Sandoz 100 mg filmsko obložene tablete	erlotinib	100 mg	Film-coated tablet	Oral use
Slovenia		Sandoz B.V.	Erlotinib Sandoz 150 mg filmsko obložene tablete	erlotinib	150 mg	Film-coated tablet	Oral use
Spain		Sandoz B.V.	Erlotinib Sandoz 25 mg, 100 mg and 150 mg comprimidos recubiertos con película EFG	erlotinib	25 mg	Film-coated tablet	Oral use
Spain		Sandoz B.V.	Erlotinib Sandoz 25 mg, 100 mg and 150 mg comprimidos recubiertos con película EFG	erlotinib	100 mg	Film-coated tablet	Oral use
Spain		Sandoz B.V.	Erlotinib Sandoz 25 mg, 100 mg and 150 mg comprimidos recubiertos con película EFG	erlotinib	150 mg	Film-coated tablet	Oral use
Spain		Brill Pharma, S.L.	Celecoxib Brill Pharma 100 mg and 200 mg cápsulas duras	celecoxib	100 mg	Capsule, hard	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Spain		Brill Pharma, S.L.	Celecoxib Brill Pharma 100 mg and 200 mg cápsulas duras	celecoxib	200 mg	Capsule, hard	Oral use
Spain		Accord Healthcare Ltd	Saquinavir Accord 500 mg comprimidos recubiertos con película EFG	saquinavir	500 mg	Film-coated tablet	Oral use
Spain	Teva Pharma, S.L.U.		Atovacuona/Hidrocloruro de Proguanil Teva 250 mg/ 100 mg comprimidos recubiertos con película EFG	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Spain	Sandoz Farmaceutica, S. A.		Atovacuona/Hidrocloruro de Proguanil Sandoz 250 mg/ 100 mg comprimidos recubiertos con película EFG	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Spain	Pensa Pharma, S.A.U.		Eprosartan Pensa 600 mg comprimidos recubiertos con película EFG	eprosartan	600 mg	Film-coated tablet	Oral use
Spain	Industria Química Y Farmacéutica VIR, S.A.		Celecoxib VIR 200 mg cápsulas duras EFG	celecoxib	200 mg	Capsule, hard	Oral use
Sweden		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
Sweden		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Sweden		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
Sweden	Sandoz A/S		Horisto	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
Sweden	Sandoz A/S		Horisto	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Sweden	Mylan AB		Eletriptan Mylan	eletriptan	20 mg	Film-coated tablet	Oral use
Sweden	Mylan AB		Eletriptan Mylan	eletriptan	40 mg	Film-coated tablet	Oral use
Sweden	Orifarm Generics A/S		Atovaquone/Proguanil Orifarm	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
Sweden	Medical Valley Invest AB		Celecoxib Medical Valley	celecoxib	100 mg	Capsule, hard	Oral use
Sweden	Medical Valley Invest AB		Celecoxib Medical Valley	celecoxib	200 mg	Capsule, hard	Oral use
The Netherlands		PharmaSwiss Česká republika s.r.o.	ERLOTIB	erlotinib	25 mg	Film-coated tablet	Oral use
The Netherlands		PharmaSwiss Česká republika s.r.o.	ERLOTIB	erlotinib	100 mg	Film-coated tablet	Oral use
The Netherlands		PharmaSwiss Česká republika s.r.o.	ERLOTIB	erlotinib	150 mg	Film-coated tablet	Oral use
The Netherlands		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
The Netherlands		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
The Netherlands		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
The Netherlands		Sandoz B.V.	Erlotinib Sandoz	erlotinib	25 mg	Film-coated tablet	Oral use
The Netherlands		Sandoz B.V.	Erlotinib Sandoz	erlotinib	100 mg	Film-coated tablet	Oral use
The Netherlands		Sandoz B.V.	Erlotinib Sandoz	erlotinib	150 mg	Film-coated tablet	Oral use
The Netherlands		Accord Healthcare Ltd	Saquinavir Accord	saquinavir	500 mg	Film-coated tablet	Oral use
The Netherlands		Teva B.V.	Erlotinib PCH	erlotinib	25 mg	Film-coated tablet	Oral use
The Netherlands		Teva B.V.	Erlotinib PCH	erlotinib	100 mg	Film-coated tablet	Oral use
The Netherlands		Teva B.V.	Erlotinib PCH	erlotinib	150 mg	Film-coated tablet	Oral use
The Netherlands	Teva Nederland B.V.		Atovaquon/Proguanil HCl Teva	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
The Netherlands	Teva Nederland B.V.		Atovaquon/Proguanil HCl Teva	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Atovaquon/Proguanil HCl Sandoz	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Atovaquon/Proguanil HCl Sandoz	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
The Netherlands	Sandoz B.V.		Atovaquon/Proguanil HCl Sandoz	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Atovaquon/Proguanil HCl Sandoz	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Saquinavir Sandoz	saquinavir	500 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Saquinavir Sandoz	saquinavir	500 mg	Film-coated tablet	Oral use
The Netherlands	Hetero Europe, S.L.		Celecoxib Hetero	celecoxib	100 mg	Capsule, hard	Oral use
The Netherlands	Hetero Europe, S.L.		Celecoxib Hetero	celecoxib	200 mg	Capsule, hard	Oral use
United Kingdom		Brown & Burk UK, Ltd.	ROSUVASTATIN 5 MG FILM-COATED TABLETS	rosuvastatin	5 mg	Film-coated tablet	Oral use
United Kingdom		Brown & Burk UK, Ltd.	ROSUVASTATIN 10 MG FILM-COATED TABLETS	rosuvastatin	10 mg	Film-coated tablet	Oral use
United Kingdom		Brown & Burk UK, Ltd.	ROSUVASTATIN 20 MG FILM-COATED TABLETS	rosuvastatin	20 mg	Film-coated tablet	Oral use
United Kingdom		Brown & Burk UK, Ltd.	ROSUVASTATIN 40 MG FILM-COATED TABLETS	rosuvastatin	40 mg	Film-coated tablet	Oral use
United Kingdom		Brown & Burk UK, Ltd.	TRAMADOL/PARACETAMOL BROWN & BURK 37,5 MG/ 325 MG FILM-COATED TABLETS	tramadol/paracetamol	37,5 mg/325 mg	Film-coated tablet	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
United Kingdom		Brown & Burk UK, Ltd.	Irbesartan/Hydrochlorothiazide Brown & Burk 150 mg/12,5 mg Film-coated tablets	irbesartan/hydrochlorothiazide	150 mg/12,5 mg	Film-coated tablet	Oral use
United Kingdom		Brown & Burk UK, Ltd.	Irbesartan/Hydrochlorothiazide Brown & Burk 300 mg/12,5 mg Film-coated tablets	irbesartan/hydrochlorothiazide	300 mg/12,5 mg	Film-coated tablet	Oral use
United Kingdom		Brown & Burk UK, Ltd.	Irbesartan/Hydrochlorothiazide Brown & Burk 300 mg/25 mg Film-coated tablets	irbesartan/hydrochlorothiazide	300 mg/25 mg	Film-coated tablet	Oral use
United Kingdom		Brown & Burk UK, Ltd.	Rasagiline Brown & Burk 1 mg Tablets	rasagiline	1 mg	Film-coated tablet	Oral use
United Kingdom		Lupin (Europe) Ltd	Duloxetine Lupin 20 mg GR capsules	duloxetine	20 mg	Capsule	Oral use
United Kingdom		Lupin (Europe) Ltd	Duloxetine Lupin 30 mg GR capsules	duloxetine	30 mg	Capsule	Oral use
United Kingdom		Lupin (Europe) Ltd	Duloxetine Lupin 40 mg GR capsules	duloxetine	40 mg	Capsule	Oral use
United Kingdom		Lupin (Europe) Ltd	Duloxetine Lupin 60 mg GR capsules	duloxetine	60 mg	Capsule	Oral use

Member State EU/ EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
United Kingdom	Teva UK Limited		MAFAMOZ 250 MG/100 MG FILM-COATED TABLETS	atovaquone/proguanil	250 mg/100 mg	Tablet	Oral use
United Kingdom	Teva UK Limited		MAFAMOZ 62,5 MG/25 MG FILM-COATED TABLETS	atovaquone/proguanil	62,5 mg/25 mg	Tablet	Oral use
United Kingdom	Sandoz Limited		REPRAPOG 62,5 MG/25 MG FILM-COATED TABLETS	atovaquone/proguanil	62,5 mg/25 mg	Film-coated tablet	Oral use
United Kingdom	Sandoz Limited		REPRAPOG 250 MG/100 MG FILM-COATED TABLETS	atovaquone/proguanil	250 mg/100 mg	Film-coated tablet	Oral use
United Kingdom	Brown & Burk UK Limited		AMOXICILLIN SUGAR FREE 3 G POWDER FOR ORAL SUSPENSION SACHETS	amoxicillin	3 443,35 mg	Powder for oral suspension	Oral use
United Kingdom	Hetero Europe, S.L.		EPROSARTAN 300 MG FILM-COATED TABLETS	eprosartan	300 mg	Film-coated tablet	Oral use
United Kingdom	Hetero Europe, S.L.		EPROSARTAN 400 MG FILM-COATED TABLETS	eprosartan	400 mg	Film-coated tablet	Oral use
United Kingdom	Hetero Europe, S.L.		EPROSARTAN 600 MG FILM-COATED TABLETS	eprosartan	600 mg	Film-coated tablet	Oral use
United Kingdom	Bristol Laboratories Limited		CELECOXIB CAPSULES, HARD 100 MG	celecoxib	100 mg	Capsule, hard	Oral use
United Kingdom	Bristol Laboratories Limited		CELECOXIB CAPSULES, HARD 200 MG	celecoxib	200 mg	Capsule, hard	Oral use
United Kingdom	Lupin (Europe) Ltd		Pregabalin Lupin 25 mg hard capsules	pregabalin	25 mg	Capsule, hard	Oral use

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