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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 July 2015 to 31 July 2015***(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of
the Council ⁽¹⁾)*

(2015/C 285/01)

⁽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
3.7.2015	Hetlioz	tasimelteon	Vanda Pharmaceuticals Limited 222 Regent Street, London W1B 5TR, United Kingdom	EU/1/15/1008	Capsule, hard	N05CH03	7.7.2015
13.7.2015	EVOTAZ	atazanavir/cobicistat	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/15/1025	Film-coated tablet	J05AR15	15.7.2015
17.7.2015	KEYTRUDA	pembrolizumab	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/15/1024	Powder for concentrate for solution for infusion	L01XC18	21.7.2015
17.7.2015	Pregabalin Zentiva	pregabalin	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/15/1021	Capsule, hard	N03AX16	21.7.2015
17.7.2015	Repatha	evolocumab	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/15/1016	Solution for injection in a pre-filled syringe	C10AX13	21.7.2015
20.7.2015	Bortezomib Accord	bortezomib	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/15/1019	Powder for solution for injection	L01XX32	23.7.2015
20.7.2015	Nivolumab BMS	nivolumab	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/15/1026	Concentrate for solution for infusion	L01XC17	23.7.2015
28.7.2015	Omidria	phenylephrine/ketorolac	Omeros London Limited Berkeley Square, London, W1J 6BD, United Kingdom	EU/1/15/1018	Concentrate for solution for intraocular irrigation	Pending	30.7.2015

— **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
3.7.2015	Lympreva	Biovest Europe Limited Evershed House, 70 Great Bridgewater St., Manchester M1 5ES, United Kingdom	—	7.7.2015

— **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
3.7.2015	ADCETRIS	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/12/794	7.7.2015
3.7.2015	Bemfola	FINOX Biotech AG Gewerbstrasse 7, FL-9496 Balzers, Liechtenstein	EU/1/13/909	8.7.2015
3.7.2015	Competact	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/06/354	7.7.2015
3.7.2015	Docetaxel Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/12/769	7.7.2015
3.7.2015	Docetaxel Kabi	Fresenius Kabi Oncology Plc. Lion Court, Farnham Road, Bordon, Hampshire GU35 0NF, United Kingdom	EU/1/12/770	7.7.2015
3.7.2015	Fampyra	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/11/699	7.7.2015
3.7.2015	GILENYA	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/11/677	7.7.2015
3.7.2015	Hemangirol	Pierre Fabre Dermatologie 45 place Abel Gance, F-92100 Boulogne, France	EU/1/14/919	7.7.2015
3.7.2015	IMBRUVICA	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/945	7.7.2015
3.7.2015	Neuraceq	Piramal Imaging Limited Langstone Technology Park, Langstone Road, Havant, Hampshire, PO9 1SA, United Kingdom	EU/1/13/906	7.7.2015

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

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

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

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

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

— **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
3.7.2015	Sonata	Meda AB Pipers väg 2A, S-170 09 Solna, Sverige	EU/1/99/102	7.7.2015
13.7.2015	Zoledronic acid Teva Generics	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/14/912	15.7.2015

— 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
3.7.2015	Canigen L4	Leptospira interrogans serogroup Canicola serovar Portland-vere/Leptospira interrogans serogroup Icterohaemorrhagiae serovar Copenhageni/Leptospira interrogans serogroup Australis serovar Bratislava/Lep-tospira kirschneri serogroup Grippotyphosa serovar Dadas	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/15/183	Suspension for injection	QI07AB01	7.7.2015
3.7.2015	Innovax-ILT	Live recombinant turkey herpesvirus (strain HVT/ILT-138), expressing the glycoproteins gD and gI of infectious laryngotracheitis virus	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/15/182	Suspension and solvent for suspension for injection	QI01AD	7.7.2015
31.7.2015	UpCard	Torasemide	Vétoquinol SA Magny-Vernois, 70200 Lure, France	EU/2/15/184	Tablet	QC03CA04	4.8.2015

— **Issuing of a marketing authorization** (Article 38 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
8.7.2015	Lodipressin	Le Vet Beheer B.V. Wilgenweg 7, NL-3421 TV Oudewater, Nederland	—	10.7.2015

— **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
13.7.2015	SevoFlo	Abbott Laboratories Ltd Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead Berkshire SL6 4XE, United Kingdom	EU/2/02/035	15.7.2015
17.7.2015	Incurin	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/00/018	21.7.2015
20.7.2015	Contacera	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/12/144	23.7.2015
28.7.2015	Poulvac E. coli	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/12/140	30.7.2015
31.7.2015	BTVPUR AlSap 2-4	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/10/108	4.8.2015
31.7.2015	Coxevac	CEVA SANTE ANIMALE 10 avenue de la Ballastière, F-33500 Libourne, France	EU/2/10/110	4.8.2015

— **Withdrawal of a marketing authorization** (Article 38 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
8.7.2015	ProMeris	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/06/064	10.7.2015
8.7.2015	ProMeris Duo	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/2/06/065	10.7.2015

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
30, Churchill Place, Canary Wharf
UK — LONDON E14 5EU

**Summary of European Union decisions on marketing authorisations in respect of medicinal products
from 1 July 2015 to 31 July 2015**

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

(2015/C 285/02)

— 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
16.7.2015	Medicinal products for human use which clinical part of bioequivalence studies were performed at GVK Biosciences Hyderabad site	See Annex I	See Annex I	See Annex I	20.7.2015
17.7.2015	Fentanyl	Fentanyl	Not applicable	Not applicable	20.7.2015
3.7.2015	Zoledronic acid	Zoledronic acid	Not applicable	Not applicable	7.7.2015

— 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
16.7.2015	Medicinal products for human use which clinical part of bioequivalence studies were performed at GVK Biosciences Hyderabad site	See Annex I	See Annex I	See Annex I	20.7.2015

⁽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, marketing authorisation holders in the Member States

Annex IA: Products for which the marketing authorisations are recommended for maintenance

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Austria	Basics GmbH Hemmelrather Weg 201 51377 Leverkusen Germany	Venlafaxine	Venlafaxin Ranbaxy 150 mg Retardkapseln	150 mg	Prolonged — re- leased capsule, hard	Oral use
Austria	Basics GmbH Hemmelrather Weg 201 51377 Leverkusen Germany	Venlafaxine	Venlafaxin Ranbaxy 75 mg Retardkapseln	75 mg	Prolonged — re- leased capsule, hard	Oral use
Austria	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxin Bluefish 75 mg Hartkapseln retardiert	75 mg	Prolonged — re- leased capsule, hard	Oral use
Austria	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxin Bluefish 150 mg Hartkapseln retardiert	150 mg	Prolonged — re- leased capsule, hard	Oral use
Austria	G.L. Pharma GmbH Schlossplatz 1 8502 Lannach Austria	Nebivolol	Nebilan 5 mg Tabletten	5 mg	Tablet	Oral use
Austria	G.L. Pharma GmbH Schlossplatz 1 8502 Lannach Austria	Nebivolol	Nebivolol G.L. 5 mg — Tabletten	5 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Austria	Ratiopharm Arzneimittel-Vertriebs-GmbH Albert-Schweitzer-Gasse 3 1140 Wien Austria	Nebivolol	NEBIVOLOL-RATIOPHARM 5 MG Tabletten	5 mg	Tablet	Oral use
Bulgaria	Alkaloid — INT d.o.o. Slandrova 4 1231 Ljubljana — Črnuče Slovenia	Levetiracetam	Lyvam	250 mg	Film-coated tablet	Oral use
Bulgaria	Alkaloid — INT d.o.o. Slandrova 4 1231 Ljubljana — Črnuče Slovenia	Levetiracetam	Lyvam	500 mg	Film-coated tablet	Oral use
Bulgaria	Alkaloid — INT d.o.o. Slandrova 4 1231 Ljubljana — Črnuče Slovenia	Levetiracetam	Lyvam	750 mg	Film-coated tablet	Oral use
Bulgaria	Alkaloid — INT d.o.o. Slandrova 4 1231 Ljubljana — Črnuče Slovenia	Levetiracetam	Lyvam	1 000 mg	Film-coated tablet	Oral use
Bulgaria	Ecopharm Group AD bul. Cherni vrah 14, bl.3 Sofia 1421 Bulgaria	Nebivolol	Nevolen	5 mg	Tablet	Oral use
Bulgaria	Ewopharma International s.r.o., Hlavna 13 Bratislava 83101 Slovakia	Fexofenadine	Ewofex	120 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Bulgaria	Ewopharma International s.r.o., Hlavna 13 Bratislava 83101 Slovakia	Fexofenadine	Ewofex	180 mg	Film-coated tablet	Oral use
Bulgaria	G.L. Pharma GmbH Schlossplatz 1 8502 Lannach Austria	Nebivolol	Nebilan	5 mg	Tablet	Oral use
Bulgaria	Neo Balkanika EOOD 35 Zemliane Str. Sofia 1618 Bulgaria	Nebivolol	Bivolet	5 mg	Tablet	Oral use
Bulgaria	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	Bosentan	Bosentan Sandoz	62,5 mg	Film-coated tablet	Oral use
Bulgaria	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	Bosentan	Bosentan Sandoz	125 mg	Film-coated tablet	Oral use
Croatia	Alkaloid d.o.o. Ulica grada Vukovara 226 F Zagreb 10000 Croatia	Levetiracetam	Lyvam 250 mg filmom obložene tablete	250 mg	Film-coated tablet	Oral use
Croatia	Alkaloid d.o.o. Ulica grada Vukovara 226 F Zagreb 10000 Croatia	Levetiracetam	Lyvam 500 mg filmom obložene tablete	500 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Croatia	Alkaloid d.o.o. Ulica grada Vukovara 226 F Zagreb 10000 Croatia	Levetiracetam	Lyvam 750 mg filmom obložene tablete	750 mg	Film-coated tablet	Oral use
Croatia	Alkaloid d.o.o. Ulica grada Vukovara 226 F Zagreb 10000 Croatia	Levetiracetam	Lyvam 1 000 mg filmom obložene tablete	1 000 mg	Film-coated tablet	Oral use
Cyprus	Delorbis Pharmaceuticals Ltd 17 Athinon Street Ergates Industrial Area 2643 Ergates P.O. Box 28629 2081 Lefkosia Cyprus	Levocetirizine hydrochloride	Zobral	5 mg	Film-coated tablet	Oral use
Czech Republic	Abdi Farma, Unipessoal Lda. Quinta da Fonte, Rua dos Malhoes 2770-071 Edificio D. Pedro I Paco de Arcos Portugal	Bosentan monohydrate	Bosentan Abdi 62,5 mg potahované tablety	62,5 mg	Film-coated tablet	Oral use
Czech Republic	Abdi Farma, Unipessoal Lda. Quinta da Fonte, Rua dos Malhoes 2770-071 Edificio D. Pedro I Paco de Arcos Portugal	Bosentan monohydrate	Bosentan Abdi 125 mg potahované tablety	125 mg	Film-coated tablet	Oral use
Czech Republic	Biofarm Sp. z o.o. ul. Wałbrzyska 13 60-198 Poznań Poland	Levocetirizine hydrochloride	Levocetirizin Biofarm 5 mg potahované tablety	5 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Czech Republic	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxine Bluefish 75 mg	75 mg	Prolonged — re- leased capsule, hard	Oral use
Czech Republic	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxine Bluefish 150 mg	150 mg	Prolonged — re- leased capsule, hard	Oral use
Czech Republic	Ewopharma International s.r.o., Hlavna 13 Bratislava 83101 Slovakia	Fexofenadine hydrochloride	Ewofex 120 mg potahované tablety	120 mg	Film-coated tablet	Oral use
Czech Republic	Ewopharma International s.r.o., Hlavna 13 Bratislava 83101 Slovakia	Fexofenadine hydrochloride	Ewofex 180 mg potahované tablety	180 mg	Film-coated tablet	Oral use
Czech Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Levetiracetam	Letiramyl 250 mg potahované tablety	250 mg	Film-coated tablet	Oral use
Czech Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Levetiracetam	Letiramyl 500 mg potahované tablety	500 mg	Film-coated tablet	Oral use
Czech Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Levetiracetam	Letiramyl 750 mg potahované tablety	750 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Czech Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Levetiracetam	Letiramyl 1 000 mg potahované tablety	1 000 mg	Film-coated tablet	Oral use
Czech Republic	Sandoz s.r.o. U Nákladového nádraží 10 130 00 Prague 3 Czech Republic	Bosentan monohydrate	Bosentan Sandoz 62,5 mg	62,5 mg	Film-coated tablet	Oral use
Czech Republic	Sandoz s.r.o. U Nákladového nádraží 10 130 00 Prague 3 Czech Republic	Bosentan monohydrate	Bosentan Sandoz 125 mg	125 mg	Film-coated tablet	Oral use
Czech Republic	Teva Pharmaceuticals CR, s.r.o. Radlická 3185/1c 150 00 Prague 5 Czech Republic	Bosentan monohydrate	Bosentan Teva 125 mg potahované tablety	125 mg	Film-coated tablet	Oral use
Denmark	Alfred E. Tiefenbacher GmbH Van-der-Smissen-Strasse 1 D-22767 Hamburg Germany	Levocetirizine	Levocetira	5 mg	Film-coated tablet	Oral use
Denmark	Alfred E. Tiefenbacher GmbH Van-der-Smissen-Strasse 1 D-22767 Hamburg Germany	Levocetirizine	Levcetin	5 mg	Film-coated tablet	Oral use
Denmark	Biofarm Sp. z o.o. ul. Wąbrzyska 13 60-198 Poznań Poland	Levocetirizine	Levrin	5 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Denmark	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxine Bluefish	75 mg	Prolonged-release capsule	Oral use
Denmark	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxine Bluefish	150 mg	Prolonged-release capsule	Oral use
Denmark	Cipla Channele Generics Limited Athenry Road, Loughrea, Co Galway Ireland	Fexofenadine	Alterfast	120 mg	Film-coated tablet	Oral use
Denmark	Cipla Channele Generics Limited Athenry Road, Loughrea, Co Galway Ireland	Fexofenadine	Alterfast	180 mg	Film-coated tablet	Oral use
Denmark	Cipla Channele Generics Limited Athenry Road, Loughrea, Co Galway Ireland	Fexofenadine	Clarifast	120 mg	Film-coated tablet	Oral use
Denmark	Cipla Channele Generics Limited Athenry Road, Loughrea, Co Galway Ireland	Fexofenadine	Clarifast	180 mg	Film-coated tablet	Oral use
Denmark	Cipla Channele Generics Limited Athenry Road, Loughrea, Co Galway Ireland	Fexofenadine	Histafast	120 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Denmark	Cipla Channele Generics Limited Athenry Road, Loughrea, Co Galway Ireland	Fexofenadine	Histafast	180 mg	Film-coated tablet	Oral use
Denmark	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Fexofenadine	Nefoxef	120 mg	Film-coated tablet	Oral use
Denmark	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Fexofenadine	Nefoxef	180 mg	Film-coated tablet	Oral use
Denmark	Norton Healthcare Ltd T/A Ivax Pharmaceuticals UK Ridings Point, Whistler Drive Castleford West Yorkshire WF10 5HX United Kingdom	Fexofenadine	Fexofenadinhydrochlorid 'Ivax'	120 mg	Film-coated tablet	Oral use
Denmark	Norton Healthcare Ltd T/A Ivax Pharmaceuticals UK Ridings Point, Whistler Drive Castleford West Yorkshire WF10 5HX United Kingdom	Fexofenadine	Fexofenadinhydrochlorid 'Ivax'	180 mg	Film-coated tablet	Oral use
Denmark	Orifarm Generics A/S PO BOX 69 DK-5260 Odense S Denmark	Metoclopramide hydrochloride	Metoclopramide Orifarm	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Denmark	Orifarm Generics A/S PO BOX 69 DK-5260 Odense S Denmark	Fexofenadine	Altifex	120 mg	Film-coated tablet	Oral use
Denmark	Orifarm Generics A/S PO BOX 69 DK-5260 Odense S Denmark	Fexofenadine	Altifex	180 mg	Film-coated tablet	Oral use
Estonia	G.L. Pharma GmbH Schlossplatz 1 8502 Lannach Austria	Nebivolol	NEBITEN 5 MG	5 mg	Tablet	Oral use
Estonia	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	VENLAFAXINE ORION	37,5 mg	Prolonged — re- leased capsule, hard	Oral use
Estonia	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	VENLAFAXINE ORION	75 mg	Prolonged — re- leased capsule, hard	Oral use
Estonia	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	VENLAFAXINE ORION	150 mg	Prolonged — re- leased capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Estonia	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	Bosentan	BOSENTAN SANDOZ	62,5 mg	Film-coated tablet	Oral use
Estonia	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	Bosentan	BOSENTAN SANDOZ	125 mg	Film-coated tablet	Oral use
Estonia	UAB Norameda Meistru 8a Vilnius LT-02189 Lithuania	Bosentan	BOSENTAN NORAMEDA 62,5 MG	62,5 mg	Film-coated tablet	Oral use
Estonia	UAB Norameda Meistru 8a Vilnius LT-02189 Lithuania	Bosentan	BOSENTAN NORAMEDA 125 MG	125 mg	Film-coated tablet	Oral use
Estonia	Wörlag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	VENLAGAMMA 75 MG	75 mg	Prolonged — re- leased capsule, hard	Oral use
Estonia	Wörlag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	VENLAGAMMA 150 MG	150 mg	Prolonged — re- leased capsule, hard	Oral use
Finland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxine Bluefish	75 mg	Prolonged — re- leased capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Finland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxine Bluefish	150 mg	Prolonged — re- leased capsule, hard	Oral use
Finland	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Fexofenadine	Nexofef	120 mg	Film-coated tablet	Oral use
Finland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine hydrochloride	VENLAFAXIN ORION	37,5 mg	Prolonged — re- leased capsule, hard	Oral use
Finland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine hydrochloride	VENLAFAXIN ORION	75 mg	Prolonged — re- leased capsule, hard	Oral use
Finland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine hydrochloride	VENLAFAXIN ORION	150 mg	Prolonged — re- leased capsule, hard	Oral use
France	Alfred E. Tiefenbacher GmbH Van-der-Smissen-Strasse 1 D-22767 Hamburg Germany	Levocetirizine	Levocetira 5 mg comprimé pelliculé	5 mg	Film-coated tablet	Oral use
France	BIOGARAN 15, boulevard Charles de Gaulle 92707 Colombes Cedex	Fexofenadine	FEXOFENADINE BIOGAR- AN 120 mg, comprimé pelliculé	120 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	BIOGARAN 15, boulevard Charles de Gaulle 92707 Colombes Cedex	Fexofenadine	FEXOFENADINE BIOGAR- AN 180 mg, comprimé pelliculé	180 mg	Film-coated tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Fexofenadine	FEXOFENADINE MYLAN 120 Film-coated Tablet	120 mg	Film-coated tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Fexofenadine	FEXOFENADINE MYLAN 180 Film-coated Tablet	180 mg	Film-coated tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Levetiracetam	LEVETIRACETAM MYLAN PHARMA 250 mg, com- primé pelliculé	250 mg	Tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Levetiracetam	LEVETIRACETAM MYLAN PHARMA 500 mg, com- primé pelliculé	500 mg	Tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Levetiracetam	LEVETIRACETAM MYLAN PHARMA 1 000 mg, com- primé pelliculé	1 000 mg	Tablet	Oral use
France	Plus Pharmacie SA 26 Boulevard Paul Vaillant-Couturier F-94200 Ivry-sur-Seine France	NEBIVOLOL	NEBIVOLOL ISOMED 5 mg, comprimé quadriséable	5 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Ranbaxy Pharmacie Generiques 11-15 Quai Dion Bouton 92800 Puteaux France	Venlafaxine	Venlafaxine Ranbaxy LP 37,5 mg, gélule à libération prolongée	37,5 mg	Prolonged — release capsule	Oral use
France	Ranbaxy Pharmacie Generiques 11-15 Quai Dion Bouton 92800 Puteaux France	Venlafaxine	Venlafaxine Ranbaxy LP 75 mg, gélule à libération prolongée	75 mg	Prolonged — release capsule	Oral use
France	Ranbaxy Pharmacie Generiques 11-15 Quai Dion Bouton 92800 Puteaux France	Venlafaxine	Venlafaxine Ranbaxy LP 150 mg, gélule à libération prolongée	150 mg	Prolonged — release capsule	Oral use
France	Ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm Germany	NEBIVOLOL	NEBIVOLOL RATIOPHARM 5 mg, comprimé quadrisé- cable	5 mg	Tablet	Oral use
France	Teva Sante Cœur Défense — 100-110 Esplanade du Général de Gaulle 92931 La Défense Cedex France	Fexofenadine	FEXOFENADINE TEVA 120 Film-coated Tablet	120 mg	Film-coated tablet	Oral use
France	Teva Sante Cœur Défense — 100-110 Esplanade du Général de Gaulle 92931 La Défense Cedex France	Fexofenadine	FEXOFENADINE TEVA 180 Film-coated Tablet	180 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	AAA-Pharma GmbH Liebknechtstrasse 33 70565 Stuttgart Germany	Venlafaxine	Venlafaxin AAA 75 mg Hartkapseln, retardiert	75 mg	Prolonged — re- leased capsule, hard	Oral use
Germany	AAA-Pharma GmbH Liebknechtstrasse 33 70565 Stuttgart Germany	Venlafaxine	Venlafaxin AAA 150 mg Hartkapseln, retardiert	150 mg	Prolonged — re- leased capsule, hard	Oral use
Germany	AAA-Pharma GmbH Liebknechtstrasse 33 70565 Stuttgart Germany	Venlafaxine	Venlafaxin AAA 37,5 mg Hartkapseln, retardiert	37,5 mg	Prolonged — re- leased capsule, hard	Oral use
Germany	Alfred E. Tiefenbacher GmbH Van-der-Smissen-Strasse 1 D-22767 Hamburg Germany	Levocetirizine	Levocetira 5 mg Filmtable- tten	5 mg	Film-coated tablet	Oral use
Germany	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxin Bluefish 75 mg Hartkapsel, retardiert	75 mg	Prolonged — re- leased capsule, hard	Oral use
Germany	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxin Bluefish 150 mg Hartkapsel, retardiert	15 mg	Prolonged — re- leased capsule, hard	Oral use
Germany	Dermapharm Aktiengesellschaft Lil-Dagover-Ring 7 82031 Grünwald Germany	Fexofenadine	Fexofenaderm 120 mg Filmtabletten	120 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Dermapharm Aktiengesellschaft Lil-Dagover-Ring 7 82031 Grünwald Germany	Fexofenadine	Fexofenaderm 180 mg Filmtabletten	180 mg	Film-coated tablet	Oral use
Germany	Farmaprojects, S.A.U. Santa Eulalia, 240-242 L'Hospitalet de Llobregat 08902 Barcelona Spain	Venlafaxine	Venlafaxin Farmaprojects 37,5 mg Hartkapseln, retar- diert	37,5 mg	Prolonged — re- leased capsule, hard	Oral use
Germany	Farmaprojects, S.A.U. Santa Eulalia, 240-242 L'Hospitalet de Llobregat 08902 Barcelona Spain	Venlafaxine	Venlafaxin Farmaprojects 75 mg Hartkapseln, retar- diert	75 mg	Prolonged — re- leased capsule, hard	Oral use
Germany	Farmaprojects, S.A.U. Santa Eulalia, 240-242 L'Hospitalet de Llobregat 08902 Barcelona Spain	Venlafaxine	Venlafaxin Farmaprojects 150 mg Hartkapseln, retar- diert	150 mg	Prolonged — re- leased capsule, hard	Oral use
Germany	G.L. Pharma GmbH Schlossplatz 1 8502 Lannach Austria	Nebivolol	NEBITEN 5 MG	5 mg	Tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Gen- erica KG Südwestpark 50 90449 Nürnberg Germany	Venlafaxine	Venlafaxin Heumann 37,5 mg Hartkapseln, retar- diert	37,5 mg	Prolonged — re- leased capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 90449 Nürnberg Germany	Venlafaxine	Venlafaxin Heumann 75 mg Hartkapseln, retardiert	75 mg	Prolonged — released capsule, hard	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 90449 Nürnberg Germany	Venlafaxine	Venlafaxin Heumann 150 mg Hartkapseln, retardiert	150 mg	Prolonged — released capsule, hard	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 90449 Nürnberg Germany	Nebivolol	Nebivolol Heumann 5 mg Tabletten	5 mg	Tablet	Oral use
Germany	Hormosan Pharma GmbH Wilhelmshoeher Str. 106 D-60389 Frankfurt 06 Hessen Germany	Levetiracetam	Levetiracetam-Hormosan 500 mg Filmtabletten	500 mg	Film-coated tablet	Oral use
Germany	Hormosan Pharma GmbH Wilhelmshoeher Str. 106 D-60389 Frankfurt 06 Hessen Germany	Levetiracetam	Levetiracetam-Hormosan 750 mg Filmtabletten	750 mg	Film-coated tablet	Oral use
Germany	Hormosan Pharma GmbH Wilhelmshoeher Str. 106 D-60389 Frankfurt 06 Hessen Germany	Levetiracetam	Levetiracetam-Hormosan 1 000 mg Filmtabletten	1 000 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Hormosan Pharma GmbH Wilhelmshoeher Str. 106 D-60389 Frankfurt 06 Hessen Germany	Levetiracetam	Levetiracetam-Hormosan 250 mg Filmtabletten	250 mg	Film-coated tablet	Oral use
Germany	Lannacher Heilmittel Ges.m.b.H. Schlossplatz 1 8502 Lannach Austria	Nebivolol	Nebivolol Lannacher 5 mg Tabletten	5 mg	Tablet	Oral use
Germany	Ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm Germany	Nebivolol	NEBIVOLOL-RATIOPHARM 5 mg	5 mg	Tablet	Oral use
Germany	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Nebivolol	Nebivolol Torrent 5 mg Ta- bletten	5 mg	Tablet	Oral use
Germany	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlafaxine retard 37,5 mg Hartkapseln, retardiert	37,5 mg	Prolonged — re- leased capsule, hard	Oral use
Germany	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlafaxine retard 75 mg Hartkapseln, retardiert	75 mg	Prolonged — re- leased capsule, hard	Oral use
Germany	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlafaxine retard 150 mg hartkapseln, retardiert	150 mg	Prolonged — re- leased capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Greece	Pharmazac SA 31 Naoussis street Athens 1447 Greece	Venlafaxine	Zacalen pr cap 75 mg/cap	75 mg	Prolonged — re- leased capsule, hard	Oral use
Greece	Pharmazac SA 31 Naoussis street Athens 1447 Greece	Venlafaxine	Zacalen pr cap 150 mg/cap	150 mg	Prolonged — re- leased capsule, hard	Oral use
Greece	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Nebivolol	Nebivolol Torrent 5 mg	5 mg	Tablet	Oral use
Hungary	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxin Bluefish 150 mg nyújtott hatóanyagleadású kemény kapszula	150 mg	Prolonged — re- leased capsule, hard	Oral use
Hungary	Ewopharma International s.r.o., Hlavna 13 Bratislava 83101 Slovakia	Fexofenadine	Ewofex 180 mg filmtabletta	180 mg	Film-coated tablet	Oral use
Hungary	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Fexofenadine	Fexgen 120 mg filmtabletta	120 mg	Film-coated tablet	Oral use
Hungary	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Fexofenadine	Fexgen 180 mg filmtabletta	180 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Hungary	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Nebivolol	Nebivolol Torrent 5 mg	5 mg	Tablet	Oral use
Hungary	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma 37,5 mg retard kemény kapszula	37,5 mg	Prolonged — re- leased capsule, hard	Oral use
Hungary	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma 75 mg retard kemény kapszula	75 mg	Prolonged — re- leased capsule, hard	Oral use
Hungary	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma 150 mg retard kemény kapszula	150 mg	Prolonged — re- leased capsule, hard	Oral use
Iceland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxine Bluefish	150 mg	Prolonged — re- leased capsule, hard	Oral use
Iceland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxine Bluefish	37,5 mg	Prolonged — re- leased capsule, hard	Oral use
Iceland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxine Bluefish	75 mg	Prolonged — re- leased capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Iceland	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Fexofenadine	Nexofef	120 mg	Film-coated tablet	Oral use
Iceland	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Fexofenadine	Nexofef	180 mg	Film-coated tablet	Oral use
Ireland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Venlafaxine hydrochloride	Venlablue XL 75 mg, prolonged release capsules, hard	75 mg	Prolonged — release capsule	Oral use
Ireland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Venlafaxine hydrochloride	Venlablue XL 150 mg, prolonged release capsules, hard	150 mg	Prolonged — release capsule	Oral use
Ireland	Chanelle Medical Dublin road Loughrea, Co. Galway Ireland	Fexofenadine hydrochloride	Fexofenadine hydrochloride 120 mg Film-coated tablets	120 mg	Film-coated tablet	Oral use
Ireland	Chanelle Medical Dublin road Loughrea, Co. Galway Ireland	Fexofenadine hydrochloride	Fexofenadine hydrochloride 180 mg Film-coated tablets	180 mg	Film-coated tablet	Oral use
Ireland	Morningside Healthcare Limited 115 Narborough Road Leicester, LE3 0PA United Kingdom	Venlafaxine hydrochloride	Vensir XL 75 mg prolonged-release hard capsules	75 mg	Prolonged — release capsule	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Ireland	Morningside Healthcare Limited 115 Narborough Road Leicester, LE3 0PA United Kingdom	Venlafaxine hydrochloride	Vensir XL 150 mg prolonged-release hard capsules	150 mg	Prolonged — release capsule	Oral use
Italy	Alfred E. Tiefenbacher GmbH Van-der-Smissen-Strasse 1 D-22767 Hamburg Germany	Levocetirizine	Levacetin 5 mg compresse rivestite con film	5 mg	Film-coated tablet	Oral use
Italy	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	VENLAFAXINA ABC	75 mg	Prolonged — released capsule, hard	Oral use
Italy	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	VENLAFAXINA ABC	150 mg	Prolonged — released capsule, hard	Oral use
Italy	Costanzafarma S.R.L. Via Taranto, 4 20142 Milan Italy	Fexofenadine	FIXODIN	120 mg	Film-coated tablet	Oral use
Italy	Costanzafarma S.R.L. Via Taranto, 4 20142 Milan Italy	Fexofenadine	FIXODIN	180 mg	Film-coated tablet	Oral use
Italy	FB Health S.p.A. Via dei Sabini, 28 63100 — Ascoli Piceno Italy	Venlafaxine	IXILANIA	75 mg	Prolonged — released capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Italy	FB Health S.p.A. Via dei Sabini, 28 63100 — Ascoli Piceno Italy	Venlafaxine	IXILANIA	150 mg	Prolonged — re- leased capsule, hard	Oral use
Italy	Germel Pharma S.P.A. Via Cantu', 11 Cinisello Balsamo Milan 20092 Italy	Nebivolol	NEBIVOLOLO GERMED	5 mg	Scored tablet	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Levetiracetam	LEVETIRACETAM MYLAN GENERIC	250 mg	Film-coated tablet	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Levetiracetam	LEVETIRACETAM MYLAN GENERIC	750 mg	Film-coated tablet	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Levetiracetam	LEVETIRACETAM MYLAN GENERIC	500 mg	Film-coated tablet	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Levetiracetam	LEVETIRACETAM MYLAN GENERIC	1 000 mg	Film-coated tablet	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Fexofenadine	FEXOFENADINA MYLAN GENERIC	120 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Fexofenadine	FEXOFENADINA MYLAN GENERICI	180 mg	Film-coated tablet	Oral use
Italy	Pensa Pharma S.P.A. Via Rossellini Ippolito, 12 20124 Milan Italy	Venlafaxine	VENLAFAXINA PENSA	75 mg	Prolonged — re- leased capsule, hard	Oral use
Italy	Pensa Pharma S.P.A. Via Rossellini Ippolito, 12 20124 Milan Italy	Venlafaxine	VENLAFAXINA PENSA	150 mg	Prolonged — re- leased capsule, hard	Oral use
Italy	Progefarm S.r.l. Largo Donegani 4/A 28100 — Novara Italy	Venlafaxine	VENLAFAXINA PROGE FARM	75 mg	Prolonged — re- leased capsule, hard	Oral use
Italy	Progefarm S.r.l. Largo Donegani 4/A 28100 — Novara Italy	Venlafaxine	VENLAFAXINA PROGE FARM	150 mg	Prolonged — re- leased capsule, hard	Oral use
Italy	Ranbaxy Italia S.P.A. Piazza Filippo Meda, 4, 3 20121 — Milano Italy	Venlafaxine	VENLAFAXINA RANBAXY GENERICI	75 mg	Prolonged — re- leased capsule, hard	Oral use
Italy	Ranbaxy Italia S.P.A. Piazza Filippo Meda, 4, 3 20121 — Milano Italy	Venlafaxine	VENLAFAXINA RANBAXY GENERICI	150 mg	Prolonged — re- leased capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Italy	Ranbaxy Italia S.P.A. Piazza Filippo Meda, 4, 3 20121 — Milano Italy	Lansoprazole	Lansoprazolo Ranbaxy 15 mg capsule rigide gastroresistenti	15 mg	Gastro-resistant tablet	Oral use
Italy	Ranbaxy Italia S.P.A. Piazza Filippo Meda, 4, 3 20121 — Milano Italy	Lansoprazole	Lansoprazolo Ranbaxy 30 mg capsule rigide gastroresistenti	30 mg	Gastro-resistant tablet	Oral use
Latvia	G.L. Pharma GmbH Schlossplatz 1 8502 Lannach Austria	Nebivolol	Nebiten	5 mg	Tablet	Oral use
Latvia	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	Venlafaxine Orion	37,5 mg	Prolonged — released capsule, hard	Oral use
Latvia	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	Venlafaxine Orion	75 mg	Prolonged — released capsule, hard	Oral use
Latvia	Ranbaxy UK Ltd 20 Balderton Street London W1K 6TL United Kingdom	Lansoprazole	Lanobax 30 mg gastro-resistant capsules, hard	30 mg	Gastro-resistant tablet	Oral use
Latvia	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	Bosentan	Bosentan Sandoz	62,5 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Latvia	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	Bosentan	Bosentan Sandoz	125 mg	Film-coated tablet	Oral use
Latvia	UAB Norameda Meistru 8a Vilnius LT-02189 Lithuania	Bosentan	Bosentan Norameda	62,5 mg	Film-coated tablet	Oral use
Latvia	UAB Norameda Meistru 8a Vilnius LT-02189 Lithuania	Bosentan	Bosentan Norameda	125 mg	Film-coated tablet	Oral use
Lithuania	G.L. Pharma GmbH Schlossplatz 1 8502 Lannach Austria	Nebivolol	Nebiten	5 mg	Tablet	Oral use
Lithuania	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	Venlafaxine Orion	37,5 mg	Prolonged — re- leased capsule, hard	Oral use
Lithuania	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	Venlafaxine Orion	75 mg	Prolonged — re- leased capsule, hard	Oral use
Lithuania	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	Venlafaxine Orion	150 mg	Prolonged — re- leased capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Lithuania	Ranbaxy UK Ltd Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE United Kingdom	Lansoprazole	LANOBAX	30 mg	Gastro-resistant tablet	Oral use
Lithuania	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	Bosentan	Bosentan Sandoz	62,5 mg	Film-coated tablet	Oral use
Lithuania	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	Bosentan	Bosentan Sandoz	125 mg	Film-coated tablet	Oral use
Lithuania	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Nebivolol	Nebivolol Torrent 5 mg	5 mg	Tablet	Oral use
Lithuania	UAB Norameda Meistru 8a Vilnius LT-02189 Lithuania	Bosentan	Bosentan Norameda	62,5 mg	Film-coated tablet	Oral use
Lithuania	UAB Norameda Meistru 8a Vilnius LT-02189 Lithuania	Bosentan	Bosentan Norameda	125 mg	Film-coated tablet	Oral use
Norway	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxin Bluefish	75 mg	Prolonged — re-leased capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Norway	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxin Bluefish	150 mg	Prolonged — re- leased capsule, hard	Oral use
Norway	Orifarm Generics A/S PO BOX 69 DK-5260 Odense S Denmark	Metoclopramide hydrochloride	Metoclopramide Orifarm	10 mg	Tablet	Oral use
Norway	Orifarm Generics A/S PO BOX 69 DK-5260 Odense S Denmark	Fexofenadine hydrochloride	Altifex	120 mg	Film-coated tablet	Oral use
Norway	Orifarm Generics A/S PO BOX 69 DK-5260 Odense S Denmark	Fexofenadine hydrochloride	Altifex	180 mg	Film-coated tablet	Oral use
Poland	Biofarm Sp. z o.o. ul. Walbrzyska 13 60-198 Poznań Poland	Levocetirizine	Zyx	5 mg	Film-coated tablet	Oral use
Poland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxine Bluefish XL	75 mg	Prolonged — re- leased capsule, hard	Oral use
Poland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxine Bluefish XL	150 mg	Prolonged — re- leased capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Celon Pharma S.A. Ogrodowa 2A, Kielpin 05-092 Łomianki, Poland	Bosentan	Bosentan Celon	125 mg	Film-coated tablet	Oral use
Poland	Farmaceutyczna Spółdzielnia Pracy Gajena Krucza 62 50-984 Wrocław Poland	Fexofenadine hydrochloride	Fexofast 120 mg	120 mg	Film-coated tablet	Oral use
Poland	Farmaceutyczna Spółdzielnia Pracy Gajena Krucza 62 50-984 Wrocław Poland	Fexofenadine hydrochloride	Fexofast 180 mg	180 mg	Film-coated tablet	Oral use
Poland	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Levetiracetam	Levetiracetam-Generics	250 mg	Film-coated tablet	Oral use
Poland	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Levetiracetam	Levetiracetam-Generics	500 mg	Film-coated tablet	Oral use
Poland	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Levetiracetam	Levetiracetam-Generics	750 mg	Film-coated tablet	Oral use
Poland	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Levetiracetam	Levetiracetam-Generics	1 000 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Fexofenadine	FexoGen	120 mg	Film-coated tablet	Oral use
Poland	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Fexofenadine	FexoGen	180 mg	Film-coated tablet	Oral use
Poland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	Oriven	37,5 mg	Prolonged — re- leased capsule, hard	Oral use
Poland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	Oriven	75 mg	Prolonged — re- leased capsule, hard	Oral use
Poland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	Oriven	150 mg	Prolonged — re- leased capsule, hard	Oral use
Poland	Ranbaxy (Poland) Sp. z o.o. Kubickiego 11 02-954 Warszawa Poland	Lansoprazole	LANBAX	15 mg	Gastro-resistant ta- blet	Oral use
Poland	Ranbaxy (Poland) Sp. z o.o. Kubickiego 11 02-954 Warszawa Poland	Lansoprazole	LANBAX	30 mg	Gastro-resistant ta- blet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Ranbaxy (Poland) Sp. z o.o. Kubickiego 11 02-954 Warszawa Poland	Venlafaxine	Venlabax MR	37,5 mg	Prolonged — release capsule	Oral use
Poland	Ranbaxy (Poland) Sp. z o.o. Kubickiego 11 02-954 Warszawa Poland	Venlafaxine	Venlabax MR	75 mg	Prolonged — release capsule	Oral use
Poland	Ranbaxy (Poland) Sp. z o.o. Kubickiego 11 02-954 Warszawa Poland	Venlafaxine	Venlabax MR	150 mg	Prolonged — release capsule	Oral use
Poland	Sandoz GmbH Biochemiestrasse 10 A-6250 Kundl Austria	Bosentan	Bosentan Sandoz	62,5 mg	Film-coated tablet	Oral use
Poland	Sandoz GmbH Biochemiestrasse 10 A-6250 Kundl Austria	Bosentan	Bosentan Sandoz	125 mg	Film-coated tablet	Oral use
Poland	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma	75 mg	Prolonged — re-leased capsule, hard	Oral use
Poland	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma	37,5 mg	Prolonged — re-leased capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma	150 mg	Prolonged — re- leased capsule, hard	Oral use
Poland	Zakłady Farmaceutyczne POLPHARMA S.A. Pelpińska 19 83-200 Starogard Gdański Poland	Fexofenadine hydrochloride	Telfexo 120 mg	120 mg	Film-coated tablet	Oral use
Poland	Zakłady Farmaceutyczne POLPHARMA S.A. Pelpińska 19 83-200 Starogard Gdański Poland	Fexofenadine hydrochloride	Telfexo 180 mg	180 mg	Film-coated tablet	Oral use
Portugal	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxina Bluefish XR	75 mg	Prolonged — re- leased capsule, hard	Oral use
Portugal	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxina Bluefish XR	150 mg	Prolonged — re- leased capsule, hard	Oral use
Portugal	Bluepharma Genéricos — Comércio de Medicamentos, S.A. São Martinho do Bispo 3045-016 Coimbra Portugal	Venlafaxine	Venlafaxina Bluepharma	150 mg	Prolonged — re- leased capsule, hard	Oral use
Portugal	Bluepharma Genéricos — Comércio de Medicamentos, S.A. São Martinho do Bispo 3045-016 Coimbra Portugal	Venlafaxine	Venlafaxina Bluepharma	75 mg	Prolonged — re- leased capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Bluepharma Genéricos — Comércio de Medicamentos, S.A. São Martinho do Bispo 3045-016 Coimbra Portugal	Venlafaxine	Venlafaxina Bluepharma	37,5 mg	Prolonged — re-leased capsule, hard	Oral use
Portugal	Eurogenus Farmacêutica, Sociedade Unipessoal, Lda. Rua Alto do Montijo, 13 — 2º Dto., Edifício Monsanto 2790-012 Carnaxide Portugal	Venlafaxine	Venlafaxina Eurogenus	37,5 mg	Prolonged — re-leased capsule, hard	Oral use
Portugal	Eurogenus Farmacêutica, Sociedade Unipessoal, Lda. Rua Alto do Montijo, 13 — 2º Dto., Edifício Monsanto 2790-012 Carnaxide Portugal	Venlafaxine	Venlafaxina Eurogenus	75 mg	Prolonged — re-leased capsule, hard	Oral use
Portugal	Eurogenus Farmacêutica, Sociedade Unipessoal, Lda. Rua Alto do Montijo, 13 — 2º Dto., Edifício Monsanto 2790-012 Carnaxide Portugal	Venlafaxine	Venlafaxina Eurogenus	150 mg	Prolonged — re-leased capsule, hard	Oral use
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Nebivolol	Nebivolol Generis	5 mg	tablet	Oral use
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Nebivolol	Nebivolol Inventis	5 mg	tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Fexofenadine	Fexofenadina Generis	180 mg	Film-coated tablet	Oral use
Portugal	Germel Farmacêutica, Lda. Rua Alto do Montijo, 13 — 1º Dto — Edifício Monsanto Portela de Carnaxide 2790-012 Portela de Carnaxide Portugal	Nebivolol	Nebivolol Germel	5 mg	Tablet	Oral use
Portugal	GP — Genéricos Portugueses, Lda. Rua Henrique Paiva Couceiro, 29 — Venda Nova 2700-451 Amadora Portugal	Nebivolol	Nebivolol GP	5 mg	tablet	Oral use
Portugal	Labesfal, Genéricos, S.A. Av. Dr Afonso Costa, nº 1370 3465-051 Campo de Besteiros Portugal	Venlafaxine hydrochloride	Venlafaxina Labesfal	37,5 mg	Prolonged — release tablet	oral use
Portugal	Labesfal, Genéricos, S.A. Av. Dr Afonso Costa, nº 1370 3465-051 Campo de Besteiros Portugal	Venlafaxine hydrochloride	Venlafaxina Labesfal	75 mg	Prolonged — release tablet	oral use
Portugal	Labesfal, Genéricos, S.A. Av. Dr Afonso Costa, nº 1370 3465-051 Campo de Besteiros Portugal	Venlafaxine hydrochloride	Venlafaxina Labesfal	150 mg	Prolonged — release tablet	oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Labesfal, Genéricos, S.A. Av. Dr Afonso Costa, n.º 1370 3465-051 Campo de Besteiros Portugal	Nebivolol	Nebivolol Labesfal	5 mg	tablet	Oral use
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Fexofenadine	Fexofenadina Mylan	120 mg	Film-coated tablet	Oral use
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Fexofenadine	Fexofenadina Mylan	180 mg	Film-coated tablet	Oral use
Portugal	Ratiopharm — Comércio e Indústria de Produtos Farmacêuticos, Lda. Lagoas Park, Edifício 5 A, Piso 2 2740-245 Porto Salvo Portugal	Nebivolol	Nebivolol Ratiopharm	5 mg	Tablet	Oral use
Romania	Ewopharma International s.r.o., Hlavna 13 Bratislava 83101 Slovakia	Fexofenadine hydrochloride	Ewofex 120 mg comprimate filmate	120 mg	Film-coated tablet	Oral use
Romania	Ewopharma International s.r.o., Hlavna 13 Bratislava 83101 Slovakia	Fexofenadine hydrochloride	Ewofex 180 mg comprimate filmate	180 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Romania	Ranbaxy UK Ltd Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE United Kingdom	Lansoprazole	LEVANT	15 mg	Gastro-resistant tablet	Oral use
Romania	Ranbaxy UK Ltd Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE United Kingdom	Lansoprazole	LEVANT	30 mg	Gastro-resistant tablet	Oral use
Romania	Terapia SA Str. Fabricii nr. 124 Cluj Napoca România	Venlafaxine	Venlafaxina Terapia 37,5 mg capsule cu eliberare prelungită	37,5 mg	Prolonged — released capsule, hard	Oral use
Romania	Terapia SA Str. Fabricii nr. 124 Cluj Napoca România	Venlafaxine	Venlafaxina Terapia 75 mg capsule cu eliberare prelungită	75 mg	Prolonged — released capsule, hard	Oral use
Romania	Terapia SA Str. Fabricii nr. 124 Cluj Napoca România	Venlafaxine	Venlafaxina Terapia 150 mg capsule cu eliberare prelungită	150 mg	Prolonged — released capsule, hard	Oral use
Romania	Torrent Pharma SRL Str. Stirbei Voda nr. 36 et. 2, biroul A, sector 1 Bucharest Romania	Nebivolol	Nebivolol Torrent com primare	5 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Romania	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma 37,5 mg capsule cu eliberare prelungita	37,5 mg	Prolonged — released capsule, hard	Oral use
Romania	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma 75 mg capsule cu eliberare prelungita	75 mg	Prolonged — released capsule, hard	Oral use
Romania	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma 150 mg capsule cu eliberare prelungita	150 mg	Prolonged — released capsule, hard	Oral use
Slovak Republic	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxine Bluefish XR 75 mg tvrdé kapsuly s predĺženým uvoľňovaním	75 mg	Prolonged — released capsule, hard	Oral use
Slovak Republic	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxine Bluefish XR 150 mg tvrdé kapsuly s predĺženým uvoľňovaním	150 mg	Prolonged — released capsule, hard	Oral use
Slovak Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Fexofenadine	Fexofenadin Generics 120 mg	120 mg	Film-coated tablet	Oral use
Slovak Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Fexofenadine	Fexofenadin Generics 180 mg	160 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Slovak Republic	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma 37,50 mg	37,5 mg	Prolonged — re- leased capsule, hard	Oral use
Slovak Republic	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma 75 mg	75 mg	Prolonged — re- leased capsule, hard	Oral use
Slovak Republic	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma 150 mg	150 mg	Prolonged — re- leased capsule, hard	Oral use
Slovenia	Alkaloid — INT d.o.o. Šlandrova 4 1231 Ljubljana — Črnuče Slovenia	Levetiracetam	Lyvam 250 mg filmsko ob- ložene tablete	250 mg	Film-coated tablet	Oral use
Slovenia	Alkaloid — INT d.o.o. Šlandrova 4 1231 Ljubljana — Črnuče Slovenia	Levetiracetam	Lyvam 500 mg filmsko ob- ložene tablete	500 mg	Film-coated tablet	Oral use
Slovenia	Alkaloid — INT d.o.o. Šlandrova 4 1231 Ljubljana — Črnuče Slovenia	Levetiracetam	Lyvam 750 mg filmsko ob- ložene tablete	750 mg	Film-coated tablet	Oral use
Slovenia	Alkaloid — INT d.o.o. Šlandrova 4 1231 Ljubljana — Črnuče Slovenia	Levetiracetam	Lyvam 1 000 mg filmsko ob- ložene tablete	1 000 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Slovenia	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	Bosentan	Bosentan Sandoz 62,5 mg filmsko obložene tablete	62,5 mg	Film-coated tablet	Oral use
Slovenia	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	Bosentan	Bosentan Sandoz 125 mg filmsko obložene tablete	125 mg	Film-coated tablet	Oral use
Slovenia	UAB Norameda Meistru 8a Vilnius LT-02189 Lithuania	Bosentan	Bosentan Norameda 125 mg filmsko obložene tablete	125 mg	Film-coated tablet	Oral use
Slovenia	UAB Norameda Meistru 8a Vilnius LT-02189 Lithuania	Bosentan	Bosentan Norameda 62,5 mg filmsko obložene tablete	62,5 mg	Film-coated tablet	Oral use
Spain	Aristo Pharma Iberia, S.L., c/Solana, 26, Torrejon de Ardoz, Madrid, 28850 Spain	Nebivolol	Nebivolol Edigen 5 mg comprimidos efg	5 mg	Tablet	Oral use
Spain	Aristo Pharma Iberia, S.L., c/Solana, 26, Torrejon de Ardoz, Madrid, 28850 Spain	Venlafaxine	Venlafaxina Retard Uriabs 150 mg capsulas duras de liberacion prolongada efg	150 mg	Prolonged — re- leased capsule, hard	Oral use
Spain	Aristo Pharma Iberia, S.L., c/Solana, 26, Torrejon de Ardoz, Madrid, 28850 Spain	Venlafaxine	Venlafaxina Retard Uriabs 75 mg capsulas duras de liberacion prolongada efg	75 mg	Prolonged — re- leased capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxina Bluefish 150 mg capsulas de liberacion prolongada efg	150 mg	Prolonged — release capsule	Oral use
Spain	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxina Bluefish 75 mg capsulas de liberacion prolongada efg	75 mg	Prolonged — release capsule	Oral use
Spain	Laboratorios Ranbaxy, S. L. U. Paseig de Gracia 9 7a Pl Barcelona 08007 Spain	Venlafaxine	Venlafaxina Retard Ranbaxygen 75 mg capsulas duras de liberacion prolongada efg	75 mg	Prolonged — released capsule, hard	Oral use
Spain	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 0PF United Kingdom	Levetiracetam	Levetiracetam Lupin 750 mg comprimidos recubiertos con pelicula efg	750 mg	Film-coated tablet	Oral use
Spain	Pharmagenus, S.A., Avda. Camí Real, 51-57, 08184 Palau-solita i Plegamans (Barcelona) Spain	Venlafaxine	Venlafaxina Retard Pharmagenus 150 mg capsulas duras de liberacion prolongada efg	150 mg	Prolonged — released capsule, hard	Oral use
Spain	Pharmagenus, S.A., Avda. Camí Real, 51-57, 08184 Palau-solita i Plegamans (Barcelona) Spain	Venlafaxine	Venlafaxina Retard Pharmagenus 75 mg capsulas duras de liberacion prolongada efg	75 mg	Prolonged — released capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	RATIOPHARM ESPAÑA, S.A. C/Anabel Segura, 11 Edificio Albatros B, 1ª planta 28108 Alcobendas (Madrid) Spain	Nebivolol	Nebivolol Ratio 5 mg comprimidos efg	5 mg	Tablet	Oral use
Spain	Teva Pharma S.L.U. C/Anabel Segura, 11 Edificio Albatros B, 1ª planta Madrid 28108 Spain	Fexofenadine	Fexofenadina Tevagen 120 mg comprimidos recubiertos con película efg	120 mg	Film-coated tablet	Oral use
Spain	Teva Pharma S.L.U. C/Anabel Segura, 11 Edificio Albatros B, 1ª planta Madrid 28108 Spain	Fexofenadine	Fexofenadina Tevagen 180 mg comprimidos recubiertos con película efg	180 mg	Film-coated tablet	Oral use
Spain	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Levetiracetam	Levetiracetam Lupin 1 000 mg comprimidos recubiertos con película efg	1 000 mg	Film-coated tablet	Oral use
Spain	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Levetiracetam	Levetiracetam Lupin 250 mg comprimidos recubiertos con película efg	250 mg	Film-coated tablet	Oral use
Spain	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Levetiracetam	Levetiracetam Lupin 500 mg comprimidos recubiertos con película efg	500 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Sweden	Alternova A/S Lodshusvej 11 DK-4230 Skælskør Denmark	Bendroflumethiazide	Bendroflumetiazid Alternova	2,5 mg	Tablet	Oral use
Sweden	Alternova A/S Lodshusvej 11 DK-4230 Skælskør Denmark	Bendroflumethiazide	Bendroflumetiazid Alternova	5 mg	Tablet	Oral use
Sweden	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxin Bluefish	37,5 mg	Prolonged — released capsule, hard	Oral use
Sweden	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxin Bluefish	75 mg	Prolonged — released capsule, hard	Oral use
Sweden	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxin Bluefish	150 mg	Prolonged — released capsule, hard	Oral use
Sweden	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Fexofenadine	Nefoxef	120 mg	Film-coated tablet	Oral use
Sweden	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Fexofenadine	Nefoxef	160 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Sweden	Orifarm Generics A/S PO BOX 69 DK-5260 Odense S Denmark	Metoclopramide hydrochloride	Metoclopramide Orifarm	10 mg	Tablet	Oral use
Sweden	Orifarm Generics A/S PO BOX 69 DK-5260 Odense S Denmark	Fexofenadine hydrochloride	Altifex	120 mg	Film-coated tablet	Oral use
Sweden	Orifarm Generics A/S PO BOX 69 DK-5260 Odense S Denmark	Fexofenadine hydrochloride	Altifex	180 mg	Film-coated tablet	Oral use
Sweden	Ranbaxy UK Ltd Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE United Kingdom	Venlafaxine	Venlafaxin Ranbaxy 150 mg depotkapsel, hård	150 mg	Prolonged — re- leased capsule, hard	Oral use
Sweden	Ranbaxy UK Ltd Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE United Kingdom	Venlafaxine	Venlafaxin Ranbaxy 75 mg depotkapsel, hård	75 mg	Prolonged — re- leased capsule, hard	Oral use
The Netherlands	Alfred E. Tiefenbacher GmbH Van-der-Smissen-Strasse 1 D-22767 Hamburg Germany	Levocetirizine	Levocetira 5 mg filmom- hulde tablet	5 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Apothecon B.V. Nijverheidsweg 3 3771 ME Barneveld The Netherlands	Fexofenadine	Fexofenadine HCL 120 A, filmomhulde tabletten 120 mg	120 mg	Film-coated tablet	Oral use
The Netherlands	Apothecon B.V. Nijverheidsweg 3 3771 ME Barneveld The Netherlands	Fexofenadine	Fexofenadine HCL 180 A, filmomhulde tabletten 120 mg	180 mg	Film-coated tablet	Oral use
The Netherlands	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxine Bluefish 37,5 mg, capsules met ver- lengde afgifte, hard	37,5 mg	Prolonged — re- leased capsule, hard	Oral use
The Netherlands	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxine Bluefish 37,5 mg, capsules met ver- lengde afgifte, hard	75 mg	Prolonged — re- leased capsule, hard	Oral use
The Netherlands	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxine Bluefish 37,5 mg, capsules met ver- lengde afgifte, hard	150 mg	Prolonged — re- leased capsule, hard	Oral use
The Netherlands	Farmaprojects, S.A.U. Santa Eulalia, 240-242 L'Hospitalet de Llobregat 08902 Barcelona Spain	Venlafaxine	Venlafaxine Farmaprojects 37,5 mg, capsules met ver- lengde afgifte, hard	37,5 mg	Prolonged — re- leased capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Farmaprojects, S.A.U. Santa Eulalia, 240-242 L'Hospitalet de Llobregat 08902 Barcelona Spain	Venlafaxine	Venlafaxine Farmaprojects 75 mg, capsules met verlengde afgifte, hard	75 mg	Prolonged — released capsule, hard	Oral use
The Netherlands	Farmaprojects, S.A.U. Santa Eulalia, 240-242 L'Hospitalet de Llobregat 08902 Barcelona Spain	Venlafaxine	Venlafaxine Farmaprojects 150 mg, capsules met verlengde afgifte, hard	150 mg	Prolonged — released capsule, hard	Oral use
The Netherlands	Mylan B.V. Dieselweg 25 3752 LB Bunschoten The Netherlands	Fexofenadine	Fexofenadine HCL Mylan 120 mg, filmomhulde tabletten	120 mg	Film-coated tablet	Oral use
The Netherlands	Mylan B.V. Dieselweg 25 3752 LB Bunschoten The Netherlands	Fexofenadine	Fexofenadine HCL Mylan 180 mg, filmomhulde tabletten	180 mg	Film-coated tablet	Oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Fexofenadine	Fexofenadine HCl 120 PCH, filmomhulde tabletten 120 mg	120 mg	Film-coated tablet	Oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Fexofenadine	Fexofenadine HCl 180 PCH, filmomhulde tabletten 120 mg	180 mg	Film-coated tablet	Oral use
The Netherlands	Ranbaxy UK Ltd Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE United Kingdom	Lansoprazole	Lansoprazol Ranbaxy 15 mg, maagsapresistente capsules	15 mg	Gastro-resistant tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Ranbaxy UK Ltd Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE United Kingdom	Lansoprazole	Lansoprazol Ranbaxy 30 mg, maagsapresistente capsules	30 mg	Gastro-resistant tablet	Oral use
The Netherlands	Ranbaxy UK Ltd Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE United Kingdom	Venlafaxine	Venlafaxine Ranbaxy 75 mg, capsules met verlengde afgifte	75 mg	Prolonged — released capsule, hard	Oral use
The Netherlands	Ranbaxy UK Ltd Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE United Kingdom	Venlafaxine	Venlafaxine Ranbaxy 150 mg, capsules met verlengde afgifte	150 mg	Prolonged — released capsule, hard	Oral use
The Netherlands	Ratiopharm Nederland B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Fexofenadine	Fexofenadine HCl ratio-pharm 120 mg, filmomhulde tabletten	120 mg	Film-coated tablet	Oral use
United Kingdom	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlablue XL 37,5 mg Prolonged Release Capsules Hard	37,5 mg	Prolonged — released capsule, hard	Oral use
United Kingdom	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlablue XL 75 mg Prolonged Release Capsules Hard	75 mg	Prolonged — released capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlablue XL 150 mg Prolonged Release Capsules Hard	150 mg	Prolonged — released capsule, hard	Oral use
United Kingdom	Chanelle Medical Dublin road Loughrea, Co. Galway Ireland	Fexofenadine	Fexofenadine 120 mg film-coated tablets	120 mg	Film-coated tablet	Oral use
United Kingdom	Chanelle Medical Dublin road Loughrea, Co. Galway Ireland	Fexofenadine	Fexofenadine 180 mg film-coated tablets	180 mg	Film-coated tablet	Oral use
United Kingdom	Forum Products Limited Crown House 2-8 Gloucester Road Redhill Surrey RH1 1FH United Kingdom	Venlafaxine hydrochloride	Foraven XL 75 mg Modified Release Capsules	75 mg	Modified-release capsule, hard	Oral use
United Kingdom	Forum Products Limited Crown House 2-8 Gloucester Road Redhill Surrey RH1 1FH United Kingdom	Venlafaxine hydrochloride	Foraven XL 150 mg Modified Release Capsules	150 mg	Modified-release capsule, hard	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Fexofenadine	Fexofenadine hydrochloride 120 mg Film-coated tablets	120 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Fexofenadine	Fexofenadine hydrochloride 180 mg Film-coated tablets	180 mg	Film-coated tablet	Oral use
United Kingdom	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 0PF United Kingdom	Levetiracetam	Levetiracetam Lupin 250 mg Film-coated tablets	250 mg	Film-coated tablet	Oral use
United Kingdom	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 0PF United Kingdom	Levetiracetam	Levetiracetam Lupin 500 mg Film-coated tablets	500 mg	Film-coated tablet	Oral use
United Kingdom	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 0PF United Kingdom	Levetiracetam	Levetiracetam Lupin 750 mg Film-coated tablets	750 mg	Film-coated tablet	Oral use
United Kingdom	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 0PF United Kingdom	Levetiracetam	Levetiracetam Lupin 1 000 mg Film-coated tablets	1 000 mg	Film-coated tablet	Oral use
United Kingdom	Morningside Healthcare Limited 115 Narborough Road Leicester, LE3 0PA United Kingdom	Venlafaxine hydrochloride	Vensir XL 75 mg Prolonged Release Hard Capsules	75 mg	Prolonged — re-leased capsule, hard	Oral use
United Kingdom	Morningside Healthcare Limited 115 Narborough Road Leicester, LE3 0PA United Kingdom	Venlafaxine hydrochloride	Vensir XL 150 mg Prolonged Release Hard Capsules	150 mg	Prolonged — re-leased capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Teva UK Limited Brampton Road Hampden Park Sussex BN22 9AG United Kingdom	Fexofenadine	Fexofenadine 120 mg film-coated tablets	120 mg	Film-coated tablet	Oral use
United Kingdom	Teva UK Limited Brampton Road Hampden Park Sussex BN22 9AG United Kingdom	Fexofenadine	Fexofenadine 180 mg film-coated tablets	180 mg	Film-coated tablet	Oral use

Annex IB: Products for which the marketing authorisations are recommended for suspension

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Austria	Arcana Arzneimittel GmbH Huetteldorfer Straße 299 1140 Wien Austria	Esomeprazole magnesium	Esomeprazol Arcana 20 mg magensaftresistente Hartkapseln	20 mg	Gastro-resistant capsule, hard	Oral use
Austria	Arcana Arzneimittel GmbH Huetteldorfer Straße 299 1140 Wien Austria	Esomeprazole magnesium	Esomeprazol Arcana 40 mg magensaftresistente Hartkapseln	40 mg	Gastro-resistant capsule, hard	Oral use
Austria	Arcana Arzneimittel GmbH Huetteldorfer Straße 299 1140 Wien Austria	Esomeprazole magnesium	Neximyl 20 mg magensaftresistente Hartkapseln	20 mg	Gastro-resistant capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Austria	Arcana Arzneimittel GmbH Huetteldorfer Straße 299 1140 Wien Austria	Esomeprazole magnesium	Neximyl 40 mg magensaftresistente Hartkapseln	40 mg	Gastro-resistant capsule, hard	Oral use
Austria	Arcana Arzneimittel GmbH Huetteldorfer Straße 299 1140 Wien Austria	Candesartan cilexetil	Candesartan Arcana 4 mg Tabletten	4 mg	Tablet	Oral use
Austria	Arcana Arzneimittel GmbH Huetteldorfer Straße 299 1140 Wien Austria	Candesartan cilexetil	Candesartan Arcana 8 mg Tabletten	8 mg	Tablet	Oral use
Austria	Arcana Arzneimittel GmbH Huetteldorfer Straße 299 1140 Wien Austria	Candesartan cilexetil	Candesartan Arcana 16 mg Tabletten	16 mg	Tablet	Oral use
Austria	Arcana Arzneimittel GmbH Huetteldorfer Straße 299 1140 Wien Austria	Candesartan cilexetil	Candesartan Arcana 32 mg Tabletten	32 mg	Tablet	Oral use
Austria	Genericon Pharma GmbH Hafnerstr. 211 8054 Graz Austria	Nebivolol	Nebivolol Genericon 5 mg Tabletten	5 mg	Tablet	Oral use
Austria	Ratiopharm Arzneimittel-Vertriebs-GmbH Albert-Schweitzer-Gasse 3 1140 Wien Austria	Desloratadine	Desloratadin ratiopharm 2,5 mg Schmelztabletten	2,5 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Austria	Ratiopharm Arzneimittel-Vertriebs-GmbH Albert-Schweitzer-Gasse 3 1140 Wien Austria	Desloratadine	Desloratadin ratiopharm 5 mg Schmelztabletten	5 mg	Orodispersible tablet	Oral use
Belgium	Apotex Europe B.V. Darwinweg 20 NL 2333 CR Leiden Netherlands	Desloratadine	Desloratadine Apotex	5 mg	Film-coated tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpsesteenweg 6A 1560 Hoeilaart Belgium	Donepezil	Donepezil Odis Mylan	5 mg	Orodispersible tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpsesteenweg 6A 1560 Hoeilaart Belgium	Donepezil	Donepezil Odis Mylan	10 mg	Orodispersible tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpsesteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan 0,5 mg Pharma	0,5 mg	Tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpsesteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan 1 mg Pharma	1 mg	Tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpsesteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan 2 mg Pharma	2 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Belgium	Mylan bvba/sprl Terhulpssteenweg 6A 1560 Hoeilaart Belgium	Candesartan	Candesartan Mylan	8 mg	Tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpssteenweg 6A 1560 Hoeilaart Belgium	Candesartan	Candesartan Mylan	16 mg	Tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpssteenweg 6A 1560 Hoeilaart Belgium	Candesartan	Candesartan Mylan	32 mg	Tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpssteenweg 6A 1560 Hoeilaart Belgium	Esomeprazole	Esomeprazole Mylan	20 mg	Gastro-resistant capsule, hard	Oral use
Belgium	Mylan bvba/sprl Terhulpssteenweg 6A 1560 Hoeilaart Belgium	Esomeprazole	Esomeprazole Mylan	40 mg	Gastro-resistant capsule, hard	Oral use
Belgium	Takeda Belgium Gentsesteenweg 615 1080 Brussels Belgium	Alendronic acid	Alendromono	70 mg	Tablet	Oral use
Belgium	Teva Pharma Belgium NV Laarstraat 16 2610 Wilrijk Belgium	Desloratadine	Desloratadine Teva	2,5 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Belgium	Teva Pharma Belgium NV Laarstraat 16 2610 Wilrijk Belgium	Desloratadine	Desloratadine Teva	5 mg	Orodispersible tablet	Oral use
Bulgaria	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirole Accord	0,5 mg	Film-coated tablet	Oral use
Bulgaria	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirole Accord	1 mg	Film-coated tablet	Oral use
Bulgaria	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirole Accord	2 mg	Film-coated tablet	Oral use
Bulgaria	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirole Accord	5 mg	Film-coated tablet	Oral use
Bulgaria	Alkaloid — INT d.o.o. Šlandrova 4 1231 Ljubljana — Črnuče Slovenia	Cefpodoxime	FOXERO	200 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Bulgaria	Aquachim AD blvd. Prof. Tsvetan Lazarov 83 Sofia 1582 Bulgaria	Quetiapine	Aquatiapine	25 mg	Film-coated tablet	Oral use
Bulgaria	Aquachim AD blvd. Prof. Tsvetan Lazarov 83 Sofia 1582 Bulgaria	Quetiapine	Aquatiapine	100 mg	Film-coated tablet	Oral use
Bulgaria	Aquachim AD blvd. Prof. Tsvetan Lazarov 83 Sofia 1582 Bulgaria	Quetiapine	Aquatiapine	200 mg	Film-coated tablet	Oral use
Bulgaria	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Esomeprazole magnesium	Esopragen	20 mg	Gastro-resistant capsule, hard	Oral use
Bulgaria	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Esomeprazole magnesium	Esopragen	40 mg	Gastro-resistant capsule, hard	Oral use
Bulgaria	Glenmark Pharmaceuticals s.r.o. Hvězdova 1716/2b 14078 Praha 4 Czech Republic	Trimetazidine	Apstar 35 mg prolonged-release tablets	35 mg	Prolonged — release tablet	Oral use
Bulgaria	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Trimetazidine	Trimetazigen MR	35 mg	Prolonged — release tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Bulgaria	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	Trimetazidine	Energotrim	35 mg	Prolonged — release tablet	Oral use
Bulgaria	Tchaikapharma Highquality Medicines 1 G. M. Dimitrov Blvd. Sofia 1172 Bulgaria	Bosentan	Pulmohyperta	62,5 mg	Film-coated tablet	Oral use
Bulgaria	Tchaikapharma Highquality Medicines 1 G. M. Dimitrov Blvd. Sofia 1172 Bulgaria	Bosentan	Pulmohyperta	125 mg	Film-coated tablet	Oral use
Croatia	Alkaloid d.o.o. Ulica grada Vukovara 226 F Zagreb 10000 Croatia	Cefpodoxime	Rexocef 200 mg filmom obložene tablete	200 mg	Film-coated tablet	Oral use
Croatia	Belupo, lijekovi i kozmetika d.d. Ulica Danica 5 Koprivnica 48000 Croatia	Desloratadine	Alerdin 2,5 mg raspadljive tablete za usta	2,5 mg	Orodispersible tablet	Oral use
Croatia	Belupo, lijekovi i kozmetika d.d. Ulica Danica 5 Koprivnica 48000 Croatia	Desloratadine	Alerdin 5 mg raspadljive tablete za usta	5 mg	Orodispersible tablet	Oral use
Croatia	Fidifarm d.o.o. Obrtnička 37, Bestovje Rakitje 10437 Croatia	Desloratadine	Sinalerg 5 mg filmom obložene tablete	5 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Croatia	Jadran Galenski Laboratorij d.d. Svilno 20, Rijeka 51000 Croatia	Desloratadine	Escontral direkt 2,5 mg raspadljiva tableta za usta	2,5 mg	Orodispersible tablet	Oral use
Croatia	Jadran Galenski Laboratorij d.d. Svilno 20, Rijeka 51000 Croatia	Desloratadine	Escontral direkt 5 mg raspadljiva tableta za usta	5 mg	Orodispersible tablet	Oral use
Croatia	PharmaS d.o.o. Radnička cesta 47 Zagreb 10000 Croatia	Tramadol/paracetamol	Tramadol/Paracetamol PharmaS 37,5 mg/325 mg filmom obložene tablete	37,5 mg/325 mg	Film-coated tablet	Oral use
Croatia	PharmaS d.o.o. Radnička cesta 47 Zagreb 10000 Croatia	Escitalopram	Escitalopram PharmaS 10 mg filmom obložene tablete	10 mg	Film-coated tablet	Oral use
Croatia	Sandoz d.o.o. Maksimirska 120 Zagreb 10000 Croatia	Trimetazidine hydrochloride	Vazidin 35 mg tablete s produljenim oslobađanjem	35 mg	Prolonged — release tablet	Oral use
Cyprus	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Alendronic acid	Alendronic Acid Accord	70 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Cyprus	Delorbis Pharmaceuticals Ltd 17 Athinon Street Ergates Industrial Area 2643 Ergates P.O. Box 28629 2081 Lefkosia Cyprus	Ertacapone	Nobat	200 mg	Film-coated tablet	Oral use
Cyprus	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan/Hctz Fair-med	160 mg/12,5 mg	Film-coated tablet	Oral use
Cyprus	Generics Pharma Hellas Ltd 577a Vouliagmenis Avenue Argyroupoli 164-51 Athens Greece	Donepezil hydrochloride	Donepezil/Generics	5 mg	Orodispersible tablet	Oral use
Cyprus	Generics Pharma Hellas Ltd 577a Vouliagmenis Avenue Argyroupoli 164-51 Athens Greece	Donepezil hydrochloride	Donepezil/Generics	10 mg	Orodispersible tablet	Oral use
Cyprus	Lambda Therapeutic Limited Sage House 319 Pinner Road, North Harrow Middlesex HA1 4HF United Kingdom	Ropinirole hydrochloride	Ropinirole Lambda	0,25 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Cyprus	Lambda Therapeutic Limited Sage House 319 Pinner Road, North Harrow Middlesex HA1 4HF United Kingdom	Ropinirole hydrochloride	Ropinirole Lambda	0,5 mg	Film-coated tablet	Oral use
Cyprus	Lambda Therapeutic Limited Sage House 319 Pinner Road, North Harrow Middlesex HA1 4HF United Kingdom	Ropinirole hydrochloride	Ropinirole Lambda	1 mg	Film-coated tablet	Oral use
Cyprus	Lambda Therapeutic Limited Sage House 319 Pinner Road, North Harrow Middlesex HA1 4HF United Kingdom	Ropinirole hydrochloride	Ropinirole Lambda	2 mg	Film-coated tablet	Oral use
Cyprus	Lambda Therapeutic Limited Sage House 319 Pinner Road, North Harrow Middlesex HA1 4HF United Kingdom	Ropinirole hydrochloride	Ropinirole Lambda	5 mg	Film-coated tablet	Oral use
Cyprus	Wockhardt UK Limited Ash Road North Wrexham Industrial Estate Wrexham LL13 9UF United Kingdom	Clopidogrel hydrochloride	Clopidogrel/Wockhardt	75 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Czech Republic	Abbott Laboratories, s.r.o. Evropská 2591/33d 160 00 Praha 6 — Hadovka Office Park Czech Republic	Escitalopram oxalate	Purcema 5 mg	5 mg	Film-coated tablet	Oral use
Czech Republic	Abbott Laboratories, s.r.o. Evropská 2591/33d 160 00 Praha 6 — Hadovka Office Park Czech Republic	Escitalopram oxalate	Purcema 10 mg	10 mg	Film-coated tablet	Oral use
Czech Republic	Abbott Laboratories, s.r.o. Evropská 2591/33d 160 00 Praha 6 — Hadovka Office Park Czech Republic	Escitalopram oxalate	Purcema 15 mg	15 mg	Film-coated tablet	Oral use
Czech Republic	Abbott Laboratories, s.r.o. Evropská 2591/33d 160 00 Praha 6 — Hadovka Office Park Czech Republic	Escitalopram oxalate	Purcema 20 mg	20 mg	Film-coated tablet	Oral use
Czech Republic	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Metformin hydrochloride	Metformin Actavis Retard 500 mg	500 mg	Prolonged — release tablet	Oral use
Czech Republic	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Metformin hydrochloride	Metformin Actavis Retard 750 mg	750 mg	Prolonged — release tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Czech Republic	Alkaloid — INT d.o.o. Šlandrova 4 1231 Ljubljana — Črnuče Slovenia	Cefpodoxime	Forexo 200 mg potahované tablety	200 mg	Film-coated tablet	Oral use
Czech Republic	Alvogen IPCo S.r.l. Rue Heienhaff 5 L-1736 Senningerberg Luxembourg	Desloratadine	Desloratadin Alvogen 5 mg potahované tablety	5 mg	Film-coated tablet	Oral use
Czech Republic	Apotex Europe B.V. Darwinweg 20 NL 2333 CR Leiden Netherlands	Trimetazidine dihydrochloride	Apo-trimetazidin 35 mg	35 mg	Prolonged — release tablet	Oral use
Czech Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Esomeprazole magnesium	Esomylan 40 mg	40 mg	Gastro-resistant capsule, hard	Oral use
Czech Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Rizatriptan benzoate	Rizatriptan Mylan 5 mg	5 mg	Orodispersible tablet	Oral use
Czech Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Rizatriptan benzoate	Rizatriptan Mylan 10 mg	10 mg	Orodispersible tablet	Oral use
Czech Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Donepezil hydrochloride	Donepezil Mylan 10 mg	10 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Czech Republic	Glenmark Pharmaceuticals s.r.o. Hvězdova 1716/2b 14078 Praha 4 Czech Republic	Trimetazidine dihydrochloride	Portora 35 mg tablety s prodlouženým uvolňováním	35 mg	Prolonged — release tablet	Oral use
Czech Republic	GNR Czech s.r.o. Slavojova 579/9 128 00 Praha 2 Czech Republic	Desloratadine	Geslora 5 mg	5 mg	Film-coated tablet	Oral use
Czech Republic	Labormed-Pharma, SA Theodor Pallady, 44B 032266 Bucharest Romania	Desloratadine	Desloratadin Labormed 2,5 mg tablety dispergovatelné v ústech	2,5 mg	Orodispersible tablet	Oral use
Czech Republic	Labormed-Pharma, SA Theodor Pallady, 44B 032266 Bucharest Romania	Desloratadine	Desloratadin Labormed 5 mg tablety dispergovatelné v ústech	5 mg	Orodispersible tablet	Oral use
Czech Republic	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Trimetazidine	Trimetazidin Mylan 35 mg	35 mg	Prolonged — release tablet	Oral use
Czech Republic	SVUS Pharma a.s. Smetanovo nábřeží 1238/20a 500 02 Hradec Králové Czech Republic	Desloratadine	Lotera 5 mg potahované tablety	5 mg	Film-coated tablet	Oral use
Denmark	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Metformin	Metformin 'Actavis PTC'	500 mg	Prolonged — release tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Denmark	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Metformin	Metformin 'Actavis PTC'	750 mg	Prolonged — release tablet	Oral use
Denmark	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Fluconazole	Fluconazol 'Bluefish'	50 mg	Capsule, hard	Oral use
Denmark	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Fluconazole	Fluconazol 'Bluefish'	150 mg	Capsule, hard	Oral use
Denmark	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Fluconazole	Fluconazol 'Bluefish'	200 mg	Capsule, hard	Oral use
Denmark	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan/hydrochlorthiazid 'Fair-Med'	160 mg/12,5 mg	Film-coated tablet	Oral use
Denmark	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan/hydrochlorthiazid 'Fair-Med'	320 mg/12,5 mg	Film-coated tablet	Oral use
Denmark	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan/hydrochlorthiazid 'Fair-Med'	320 mg/25 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Denmark	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Eletriptan	Eletriptan Mylan	40 mg	Film-coated tablet	Oral use
Denmark	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Esomeprazole	Esomeprazol Mylan	20 mg	Gastro-resistant capsule, hard	Oral use
Denmark	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Esomeprazole	Esomeprazol Mylan	40 mg	Gastro-resistant capsule, hard	Oral use
Denmark	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Rizatriptan	Rizatriptan Mylan	10 mg	Orodispersible tablet	Oral use
Denmark	Stadapharm GmbH Stadastr. 2-18 D-61118 Bad Vilbel Germany	Entacapone	Entacapon STADA	200 mg	Film-coated tablet	Oral use
Estonia	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Alendronic acid	ALENDRONIC ACID ACCORD 70 mg	70 mg	Tablet	Oral use
Estonia	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	Trimetazidine	ZIDMETIN	35 mg	Modified-release tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Finland	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Metformin	Metformin Actavis	500 mg	Prolonged — release tablet	Oral use
Finland	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Metformin	Metformin Actavis	750 mg	Prolonged — release tablet	Oral use
Finland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Fluconazole	Fluconazol Bluefish	50 mg	Capsule, hard	Oral use
Finland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Fluconazole	Fluconazol Bluefish	150 mg	Capsule, hard	Oral use
Finland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Fluconazole	Fluconazol Bluefish	200 mg	Capsule, hard	Oral use
Finland	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Eletriptan	Eletriptan Mylan	40 mg	Film-coated tablet	Oral use
Finland	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Repaglinide	Repaglinid Mylan	0,5 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Finland	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Repaglinide	Repaglinid Mylan	1 mg	Tablet	Oral use
Finland	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Repaglinide	Repaglinid Mylan	2 mg	Tablet	Oral use
Finland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	VALSARTAN ORION	40 mg	Film-coated tablet	Oral use
Finland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	VALSARTAN ORION	80 mg	Film-coated tablet	Oral use
Finland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	VALSARTAN ORION	160 mg	Film-coated tablet	Oral use
Finland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	VALSARTAN ORION	320 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Finland	Ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm Germany	Desloratadine	Desloratadine Ratiopharm	2,5 mg	Orodispersible tablet	Oral use
Finland	Ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm Germany	Desloratadine	Desloratadine Ratiopharm	5 mg	Orodispersible tablet	Oral use
France	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	ESCITALOPRAM ABBOTT 5 mg, comprimé pelliculé	5 mg	Film-coated tablet	Oral use
France	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	ESCITALOPRAM ABBOTT 10 mg, comprimé pelliculé	10 mg	Film-coated tablet	Oral use
France	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	ESCITALOPRAM ABBOTT 15 mg, comprimé pelliculé	15 mg	Film-coated tablet	Oral use
France	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	ESCITALOPRAM ABBOTT 20 mg, comprimé pelliculé	20 mg	Film-coated tablet	Oral use
France	ACCORD HEALTHCARE France SAS 45 Rue de Fbg de Roubaix 59000 Lille France	Ropinirole	Ropinirole Accord 0,25 mg, comprimé pelliculé	0,25 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	ACCORD HEALTHCARE France SAS 45 Rue de Fbg de Roubaix 59000 Lille France	Ropinirole	Ropinirole Accord 0,5 mg, comprimé pelliculé	0,5 mg	Film-coated tablet	Oral use
France	ACCORD HEALTHCARE France SAS 45 Rue de Fbg de Roubaix 59000 Lille France	Ropinirole	Ropinirole Accord 1 mg, comprimé pelliculé	1 mg	Film-coated tablet	Oral use
France	ACCORD HEALTHCARE France SAS 45 Rue de Fbg de Roubaix 59000 Lille France	Ropinirole	Ropinirole Accord 2 mg, comprimé pelliculé	2 mg	Film-coated tablet	Oral use
France	ACCORD HEALTHCARE France SAS 45 Rue de Fbg de Roubaix 59000 Lille France	Ropinirole	Ropinirole Accord 5 mg, comprimé pelliculé	5 mg	Film-coated tablet	Oral use
France	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram	ESCITALOPRAM BROWN 5 mg, comprimé pelliculé sécable	5 mg	Film-coated tablet	Oral use
France	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram	ESCITALOPRAM BROWN 10 mg, comprimé pelliculé sécable	10 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram	ESCITALOPRAM BROWN 15 mg, comprimé pelliculé sécable	15 mg	Film-coated tablet	Oral use
France	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram	ESCITALOPRAM BROWN 20 mg, comprimé pelliculé sécable	20 mg	Film-coated tablet	Oral use
France	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Ebastine	EBASTINE BROWN & BURK 10 mg, comprimé orodispersible	10 mg	Orodispersible tablet	Oral use
France	Cristers 22, quai Galliéni 92150 Suresnes France	Desloratadine	DESLOTATADINE CRISTERS 5 mg comprimé pelliculé	5 mg	Film-coated tablet	Oral use
France	Cristers 22, quai Galliéni 92150 Suresnes France	Ibuprofen	IBUPROFENE CRISTERS 400 mg comprimé pelliculé	400 mg	Film-coated tablet	Oral use
France	Laboratoires Biogaran 15, boulevard Charles de Gaulle 92707 Colombes Cedex France	Ebastine	EBASTINE BIOGARAN 10 mg comprimé pelliculé	10 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Laboratoires Biogaran 15, boulevard Charles de Gaulle 92707 Colombes Cedex France	Ebastine	EBASTINE BIOGARAN 10 mg comprimé orodispersible	10 mg	Orodispersible tablet	Oral use
France	Laboratoires GERDA 24 rue Erlanger 75016 PARIS France	Desloratadine	DESLOTATADINE ARROW 5 mg comprimé pelliculé	5 mg	Film-coated tablet	Oral use
France	Medipha Sante Les Fjords — Immeuble Oslo 19 avenue de Norvège 91953 Courtaboeuf Cedex France	Tramadol/paracetamol	TRAMADOL PARACETAMOL NIA- LEX 37,5 mg/325 mg comprimé pelliculé	37,5 mg/325 mg	Film-coated tablet	Oral use
France	Medipha Sante Les Fjords — Immeuble Oslo 19 avenue de Norvège 91953 Courtaboeuf Cedex France	Desloratadine	DESLOTATADINE GNR 5 mg comprimé pelliculé	5 mg	Film-coated tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Rizatriptan	RIZATRIPTAN MYLAN 5 mg, or- odispersible tablet	5 mg	Orodispersible tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Rizatriptan	RIZATRIPTAN MYLAN 10 mg, or- odispersible tablet	10 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Ebastine	EBASTINE MYLAN 10 mg, film-coated tablet	10 mg	Film-coated tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Ebastine	EBASTINE MYLAN 10 mg, orodispersible tablet	10 mg	Orodispersible tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Trimetazidine	TRIMETAZIDINE MYLAN 35 mg Modified Release Tablets	35 mg	Modified-release tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Candesartan	CANDESARTAN MYLAN 32 mg, comprimé sécable	32 mg	Tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Donepezil	DONEPEZIL MYLAN 5 mg, orodispersible tablet	5 mg	Orodispersible tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Donepezil	DONEPEZIL MYLAN 10 mg, orodispersible tablet	10 mg	Orodispersible tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Esomeprazole	ESOMEPRAZOLE MYLAN PHARMA 20 mg, DR capsule	20 mg	Gastro-resistant capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Esomeprazole	ESOMEPRAZOLE MYLAN PHARMA 40 mg, DR capsule	40 mg	Gastro-resistant capsule, hard	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Desmopressin	DESMOPRESSINE MYLAN 60 µg, orodispersible tablet	0,06 mg	Orodispersible tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Desmopressin	DESMOPRESSINE MYLAN 120 µg, orodispersible tablet	0,12 mg	Orodispersible tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Desmopressin	DESMOPRESSINE MYLAN 240 µg, orodispersible tablet	0,24 mg	Orodispersible tablet	Oral use
France	Ranbaxy Pharmacie Generiques 11-15 Quai Dion Bouton 92800 Puteaux France	Aciclovir	Aciclovir Ranbaxy 800 mg, comprimé	800 mg	Tablet	Oral use
France	Ranbaxy Pharmacie Generiques 11-15 Quai Dion Bouton 92800 Puteaux France	Aciclovir	Aciclovir Ranbaxy 200 mg, comprimé	200 mg	Tablet	Oral use
France	Ranbaxy Pharmacie Generiques 11-15 Quai Dion Bouton 92800 Puteaux France	Aciclovir	Aciclovir Almus 200 mg, comprimé	200 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Ranbaxy Pharmacie Generiques 11-15 Quai Dion Bouton 92800 Puteaux France	Alendronic acid	Acide Alendronique Ranbaxy 70 mg, comprimé	70 mg	Tablet	Oral use
France	Sanofi Aventis France 1-13 bd Romain Rolland 75159 Paris Cedex 14 France	Ebastine	EBASTINE ZENTIVA 10 mg com- primé pelliculé	10 mg	Film-coated tablet	Oral use
France	Sanofi Aventis France 1-13 bd Romain Rolland 75159 Paris Cedex 14 France	Ebastine	EBASTINE ZENTIVA 10 mg com- primé orodispersible	10 mg	Orodispersible tablet	Oral use
France	Teva Sante Cœur Défense — 100-110 Esplanade du Général de Gaulle 92931 La Défense Cedex France	Desloratadine	DES LorATADINE TEVA SANTE 5 mg comprimé pelliculé	5 mg	Film-coated tablet	Oral use
France	Venipharm SAS 4 Bureaux de la Colline 92213 Saint-Cloud France	Ebastine	EBOUDA 10 mg comprimé pelli- culé	10 mg	Film-coated tablet	Oral use
France	Venipharm SAS 4 Bureaux de la Colline 92213 Saint-Cloud France	Ebastine	EBARREN 10 mg comprimé pelli- culé	10 mg	Film-coated tablet	Oral use
France	Venipharm SAS 4 Bureaux de la Colline 92213 Saint-Cloud France	Ebastine	EBONDE 10 mg comprimé pelliculé	10 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Venipharm SAS 4 Bureaux de la Colline 92213 Saint-Cloud France	Ebastine	EBONTAN 10 mg comprimé oro-dispersible	10 mg	Orodispersible tablet	Oral use
France	Venipharm SAS 4 Bureaux de la Colline 92213 Saint-Cloud France	Ebastine	EBACHOI 10 mg comprimé oro-dispersible	10 mg	Orodispersible tablet	Oral use
France	Venipharm SAS 4 Bureaux de la Colline 92213 Saint-Cloud France	Ibuprofen	IBUPROFENE ZYDUS FRANCE 200 mg comprimé pelliculé	200 mg	Film-coated tablet	Oral use
France	Zydus France Zacles Hautes Patures 25 Rue des Peupliers 92752 Nanterre Cedex France	Ibuprofen	IBUPROFENE ZYDUS FRANCE 400 mg comprimé pelliculé	400 mg	Film-coated tablet	Oral use
France	Zydus France Zacles Hautes Patures 25 Rue des Peupliers 92752 Nanterre Cedex France	Tramadol/paracetamol	TRAMADOL PARACETAMOL ZYDUS FRANCE 37,5 mg/325 mg comprimé pelliculé	37,5 mg/325 mg	Film-coated tablet	Oral use
France	Zydus France Zacles Hautes Patures 25 Rue des Peupliers 92752 Nanterre Cedex France	Ibuprofen	IBUPROFENE ZF 400 mg comprimé pelliculé	400 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Zydus France Zacles Hautes Patures 25 Rue des Peupliers 92752 Nanterre Cedex France	Desloratadine	DESLOTATADINE ZYDUS 5 mg comprimé pelliculé	5 mg	Film-coated tablet	Oral use
France	Zydus France Zacles Hautes Patures 25 Rue des Peupliers 92752 Nanterre Cedex France	Escitalopram	ESCITALOPRAM ZYDUS 5 mg, comprimé pelliculé	5 mg	Film-coated tablet	Oral use
France	Zydus France Zacles Hautes Patures 25 Rue des Peupliers 92752 Nanterre Cedex France	Escitalopram	ESCITALOPRAM ZYDUS 10 mg, comprimé pelliculé sécable	10 mg	Film-coated tablet	Oral use
France	Zydus France Zacles Hautes Patures 25 Rue des Peupliers 92752 Nanterre Cedex France	Escitalopram	ESCITALOPRAM ZYDUS 15 mg, comprimé pelliculé sécable	15 mg	Film-coated tablet	Oral use
France	Zydus France Zacles Hautes Patures 25 Rue des Peupliers 92752 Nanterre Cedex France	Escitalopram	ESCITALOPRAM ZYDUS 20 mg, comprimé pelliculé sécable	20 mg	Film-coated tablet	Oral use
Germany	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Alendronic acid	ALENDRONIC ACID ACCORD 70 MG	70 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Betapharm Arzneimittel GmbH Kobelweg 95 D-86156 Augsburg Germany	Levetiracetam	Levetiracetam beta 250 mg, Filmtabletten	250 mg	Film-coated tablet	Oral use
Germany	Betapharm Arzneimittel GmbH Kobelweg 95 D-86156 Augsburg Germany	Levetiracetam	Levetiracetam beta 500 mg, Filmtabletten	500 mg	Film-coated tablet	Oral use
Germany	Betapharm Arzneimittel GmbH Kobelweg 95 D-86156 Augsburg Germany	Levetiracetam	Levetiracetam beta 750 mg, Filmtabletten	750 mg	Film-coated tablet	Oral use
Germany	Betapharm Arzneimittel GmbH Kobelweg 95 D-86156 Augsburg Germany	Levetiracetam	Levetiracetam beta 1 000 mg, Filmtabletten	1 000 mg	Film-coated tablet	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan	Irbesartan Tablets 75 mg	75 mg	Film-coated tablet	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan	Irbesartan Tablets 150 mg	150 mg	Film-coated tablet	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan	Irbesartan Tablets 300 mg	300 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan HCTZ Fair-Med 150 + 12,5 mg Filmtabletten	150 mg/12,5 mg	Film-coated tablet	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan HCTZ Fair-Med 300 + 12,5 mg Filmtabletten	300 mg/12,5 mg	Film-coated tablet	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan HCTZ Fair-Med 300 + 25 mg Filmtabletten	300 mg/25 mg	Film-coated tablet	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan/HCTZ Fair-Med Health-care 160 mg/12,5 mg Filmtabletten	160 mg/12,5 mg	Film-coated tablet	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan/HCTZ Fair-Med Health-care 320 mg/12,5 mg Filmtabletten	320 mg/12,5 mg	Film-coated tablet	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan/HCTZ Fair-Med Health-care 320 mg/25 mg Filmtabletten	320 mg/25 mg	Film-coated tablet	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Venlafaxine	Venlafaxin Fair-Med 37,5 mg Hartkapseln, retardiert	37,5 mg	Prolonged — release capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Venlafaxine	Venlafaxin Fair-Med 75 mg Hart- kapseln, retardiert	75 mg	Prolonged — release capsule, hard	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Venlafaxine	Venlafaxin Fair-Med 150 mg Hart- kapseln, retardiert	150 mg	Prolonged — release capsule, hard	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Ciprofloxacin	Ciprofloxacin Fair-Med Healthcare 500 mg Filmtabletten	500 mg	Film-coated tablet	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Ciprofloxacin	Ciprofloxacin Fair-Med Healthcare 750 mg Filmtabletten	750 mg	Film-coated tablet	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Ciprofloxacin	Ciprofloxacin Fair-Med Healthcare 250 mg Filmtabletten	250 mg	Film-coated tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Gen- erica KG Südwestpark 50 90449 Nürnberg Germany	Irbesartan	Irbesartan Heumann 75 mg Filmta- bletten	75 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Heumann Pharma GmbH & Co. Gen- erica KG Südwestpark 50 90449 Nürnberg Germany	Irbesartan	Irbesartan Heumann 150 mg Film- tabletten	150 mg	Film-coated tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Gen- erica KG Südwestpark 50 90449 Nürnberg Germany	Irbesartan	Irbesartan Heumann 300 mg Film- tabletten	300 mg	Film-coated tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Gen- erica KG Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydrochlor- othiazide	Irbesartan/Hydrochlorothiazid Heu- mann 150 mg/12,5 mg Filmtable- tten	150 mg/12,5 mg	Film-coated tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Gen- erica KG Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydrochlor- othiazide	Irbesartan/Hydrochlorothiazid Heu- mann 300 mg/12,5 mg Filmtable- tten	300 mg/12,5 mg	Film-coated tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Gen- erica KG Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydrochlor- othiazide	Irbesartan/Hydrochlorothiazid Heu- mann 300 mg/25 mg Filmtabletten	300 mg/25 mg	Film-coated tablet	Oral use
Germany	Hormosan Pharma GmbH Wilhelmshoeher Str. 106 D-60389 Frankfurt 06 Hessen Germany	Cefpodoxime proxetil	Cefpodoxim- Hormosan 200 mg Filmtabletten	200 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 0PF United Kingdom	Trimetazidine hydrochloride	Lupomadazine 35 mg Retardtabletten	35 mg	Controlled — release tablet	Oral use
Germany	Micro Labs GmbH Lyoner Str. 14 D-60528 Frankfurt/Main Germany	Escitalopram	Escitalopram-Micro Labs 5 mg Filmtabletten	5 mg	Film-coated tablet	Oral use
Germany	Micro Labs GmbH Lyoner Str. 14 D-60528 Frankfurt/Main Germany	Escitalopram	Escitalopram-Micro Labs 10 mg Filmtabletten	10 mg	Film-coated tablet	Oral use
Germany	Micro Labs GmbH Lyoner Str. 14 D-60528 Frankfurt/Main Germany	Escitalopram	Escitalopram-Micro Labs 15 mg Filmtabletten	15 mg	Film-coated tablet	Oral use
Germany	Micro Labs GmbH Lyoner Str. 14 D-60528 Frankfurt/Main Germany	Escitalopram	Escitalopram-Micro Labs 20 mg Filmtabletten	20 mg	Film-coated tablet	Oral use
Germany	Mylan dura GmbH Wittichstrasse 6 64295 Darmstadt Germany	Repaglinide	Repaglinid Mylan 0,5 mg Tabletten	0,5 mg	Tablet	Oral use
Germany	Mylan dura GmbH Wittichstrasse 6 64295 Darmstadt Germany	Repaglinide	Repaglinid Mylan 1 mg Tabletten	1 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Mylan dura GmbH Wittichstrasse 6 64295 Darmstadt Germany	Repaglinide	Repaglinid Mylan 2 mg Tabletten	2 mg	Tablet	Oral use
Germany	Mylan dura GmbH Wittichstrasse 6 64295 Darmstadt Germany	Rizatriptan	Rizatriptan Mylan dura 5 mg Schmelztabletten	5 mg	Orodispersible tablet	Oral use
Germany	Mylan dura GmbH Wittichstrasse 6 64295 Darmstadt Germany	Rizatriptan	Rizatriptan Mylan dura 10 mg Schmelztabletten	10 mg	Orodispersible tablet	Oral use
Germany	Panacea Biotec Germany GmbH Landshuter Allee 8-10 D-80637 München Germany	Tacrolimus	Tacpan 0,5 mg Hartkapseln	0,5 mg	Capsule, hard	Oral use
Germany	Panacea Biotec Germany GmbH Landshuter Allee 8-10 D-80637 München Germany	Tacrolimus	Tacpan 1 mg Hartkapseln	1 mg	Capsule, hard	Oral use
Germany	Panacea Biotec Germany GmbH Landshuter Allee 8-10 D-80637 München Germany	Tacrolimus	Tacpan 5 mg Hartkapseln	5 mg	Capsule, hard	Oral use
Germany	Stadapharm GmbH Stadastr. 2-18 D-61118 Bad Vilbel Germany	Entacapone	Entacapon STADA 200 mg Filmtabletten	200 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Unichem Laboratories Ltd Studio 8B Ard Gaoithe Commercial Centre, Business Park Cashel Road Clonmel, Co Tipperary Ireland	Irbesartan	Irbesartan Unichem 150 mg Film-tabletten	150 mg	Film-coated tablet	Oral use
Germany	Unichem Laboratories Ltd Studio 8B Ard Gaoithe Commercial Centre, Business Park Cashel Road Clonmel, Co Tipperary Ireland	Irbesartan	Irbesartan Unichem 300 mg Film-tabletten	300 mg	Film-coated tablet	Oral use
Germany	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan + Hydrochlorotiazida Welding	300 mg/12,5 mg	Film-coated tablet	Oral use
Germany	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan + Hydrochlorotiazida Welding	150 mg/12,5 mg	Film-coated tablet	Oral use
Germany	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan + Hydrochlorotiazida Welding	300 mg/25 mg	Film-coated tablet	Oral use
Germany	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan	Irbesartan Welding	75 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan	Irbesartan Welding	150 mg	Film-coated tablet	Oral use
Germany	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan	Irbesartan Welding	300 mg	Film-coated tablet	Oral use
Greece	Abbott Laboratories Hellas ABEE Agiou Dimitriou 63 Alimos 17456 Greece	Escitalopram oxalate	Savandra	5 mg	Film-coated tablet	Oral use
Greece	Abbott Laboratories Hellas ABEE Agiou Dimitriou 63 Alimos 17456 Greece	Escitalopram oxalate	Savandra	10 mg	Film-coated tablet	Oral use
Greece	Abbott Laboratories Hellas ABEE Agiou Dimitriou 63 Alimos 17456 Greece	Escitalopram oxalate	Savandra	15 mg	Film-coated tablet	Oral use
Greece	Abbott Laboratories Hellas ABEE Agiou Dimitriou 63 Alimos 17456 Greece	Escitalopram oxalate	Savandra	20 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Greece	Genepharm S.A. 18 Km Marathon Avenue, 15351 Pallini Greece	Desloratadine	Desloratadine/Genepharm 5 mg δισκία επικαλυμμένα με υμένιο,	5 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A. 18 Km Marathon Avenue, 15351 Pallini Greece	Desloratadine	Desloratadine/Genepharm 2,5 mg δισκία διασπειρόμενα στο στόμα	2,5 mg	Orodispersible tablet	Oral use
Greece	Genepharm S.A. 18 Km Marathon Avenue, 15351 Pallini Greece	Desloratadine	Desloratadine/Genepharm 5 mg δισκία διασπειρόμενα στο στόμα	5 mg	Orodispersible tablet	Oral use
Greece	Generics Pharma Hellas Ltd 577a Vouliagmenis Avenue Argyroupoli 164-51 Athens Greece	Donepezil hydrochloride	Donepezil/ Generics	5 mg	Orodispersible tablet	Oral use
Greece	Generics Pharma Hellas Ltd 577a Vouliagmenis Avenue Argyroupoli 164-51 Athens Greece	Donepezil hydrochloride	Donepezil/ Generics	10 mg	Orodispersible tablet	Oral use
Greece	Generics Pharma Hellas Ltd 577a Vouliagmenis Avenue Argyroupoli 164-51 Athens Greece	Esomeprazole magnesium	Esomeprazole/ Generics	40 mg	Prolonged — release capsule	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Greece	Sieger Pharma A.E. Marathonos Avenue 106 Pikermi 19009 Greece	Desloratadine	Desloratadine/Sieger	5 mg	Film-coated tablet	Oral use
Greece	Sieger Pharma A.E. Marathonos Avenue 106 Pikermi 19009 Greece	Desloratadine	Desloratadine/Sieger	2,5 mg	Orodispersible tablet	Oral use
Greece	Sieger Pharma A.E. Marathonos Avenue 106 Pikermi 19009 Greece	Desloratadine	Desloratadine/Sieger	5 mg	Orodispersible tablet	Oral use
Hungary	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Metformin hydrochloride	Gluforlyn XR 500 mg retard tabletta	500 mg	Prolonged — release tablet	Oral use
Hungary	Alvogen IPCo S.r.l. Rue Heienhaff 5 L-1736 Senningerberg Luxembourg	Desloratadine	Alvotadin 5 mg filmtabletta	5 mg	Film-coated tablet	Oral use
Hungary	Alvogen IPCo S.r.l. Rue Heienhaff 5 L-1736 Senningerberg Luxembourg	Desloratadine	Alvotadin 2,5 mg szájban diszpergálódó tabletta	2,5 mg	Orodispersible tablet	Oral use
Hungary	Alvogen IPCo S.r.l. Rue Heienhaff 5 L-1736 Senningerberg Luxembourg	Desloratadine	Alvotadin 5 mg szájban diszpergálódó tabletta	5 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Hungary	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Esomeprazole magnesium	Esomeprazol Mylan 20 mg gyomordv-ellenálló kemény kapszula	20 mg	Gastro-resistant capsule, hard	Oral use
Hungary	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Esomeprazole magnesium	Esomeprazol Mylan 40 mg gyomordv-ellenálló kemény kapszula	40 mg	Gastro-resistant capsule, hard	Oral use
Hungary	Glenmark Pharmaceuticals s.r.o. Hvězdova 1716/2b 14078 Praha 4 Czech Republic	Trimetazidine dihydrochloride	Apstar 35 mg retard tabletta	35 mg	Prolonged — release tablet	Oral use
Hungary	Goodwill Pharma Kft. H-6724 Szeged Cserzy Mihály u. 32. Hungary	Desloratadine	Inaller 5 mg filmtabletta	5 mg	Film-coated tablet	Oral use
Hungary	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Trimetazidine	Trimetazidine Mylan 35 mg retard tabletta	35 mg	Prolonged — release tablet	Oral use
Hungary	Sandoz Hungária Kft. H-1114 Budapest Bartók Béla út 43-47. Hungary	Trimetazidine dihydrochloride	Trimetazidine Sandoz 35 mg retard tabletta	35 mg	Prolonged — release tablet	Oral use
Hungary	Teva Gyógyszergyár Zrt. H-4042 Debrecen Pallagi út 13. Hungary	Desloratadine	Desloratadin Teva 2,5 mg szájban diszpergalódó tabletta	2,5 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Hungary	Teva Gyógyszergyár Zrt. H-4042 Debrecen Pallagi út 13. Hungary	Desloratadine	Desloratadin Teva 5 mg szájban diszpergálódó tabletta	5 mg	Orodispersible tablet	Oral use
Iceland	Ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm Germany	Desloratadine	Desloratadine ratiopharm	5 mg	Orodispersible tablet	Oral use
Ireland	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole hydro- chloride	Ropinirole 0,25 mg Film-coated Tablets	0,25 mg	Film-coated tablet	Oral use
Ireland	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole hydro- chloride	Ropinirole 0,5 mg Film-coated Ta- blets	0,5 mg	Film-coated tablet	Oral use
Ireland	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole hydro- chloride	Ropinirole 1 mg Film-coated Tablets	1 mg	Film-coated tablet	Oral use
Ireland	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole hydro- chloride	Ropinirole 2 mg Film-coated Tablets	2 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Ireland	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole hydrochloride	Ropinirole 5 mg Film-coated Tablets	5 mg	Film-coated tablet	Oral use
Ireland	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Alendronic acid	Alendronic Acid Once Weekly 70 mg Tablets	70 mg	Tablet	Oral use
Ireland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan/Hydrochlorothiazide Fair-Med 160 mg/12,5 mg film-coated tablets.	160 mg/12,5 mg	Film-coated tablet	Oral use
Ireland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan/Hydrochlorothiazide Fair-Med 320 mg/12,5 mg film-coated tablets	320 mg/12,5 mg	Film-coated tablet	Oral use
Ireland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan/Hydrochlorothiazide Fair-Med 320 mg/25 mg film-coated tablets	320 mg/25 mg	Film-coated tablet	Oral use
Ireland	Fannin (UK) Ltd 42-46 Booth Drive Park Farm South Wellingborough Northamptonshire NN8 6GT United Kingdom	Fexofenadine hydrochloride	Fexofenadine 120 mg film-coated tablets	120 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Ireland	Fanin (UK) Ltd 42-46 Booth Drive Park Farm South Wellingborough Northamptonshire NN8 6GT United Kingdom	Fexofenadine hydrochloride	Fexofenadine 180 mg film-coated tablets	180 mg	Film-coated tablet	Oral use
Ireland	McDermott Laboratories Ltd t/a Gerard Laboratories 35/36 Baldoye Industrial Estate Grange Road Dublin 13 Ireland	Donepezil	Aripil Orotab 5 mg Orodispersible Tablet	5 mg	Orodispersible tablet	Oral use
Ireland	McDermott Laboratories Ltd t/a Gerard Laboratories 35/36 Baldoye Industrial Estate Grange Road Dublin 13 Ireland	Donepezil	Aripil Orotab 10 mg Orodispersible Tablet	10 mg	Orodispersible tablet	Oral use
Ireland	McDermott Laboratories Ltd t/a Gerard Laboratories 35/36 Baldoye Industrial Estate Grange Road Dublin 13 Ireland	Esomeprazole	Esomeprazole Mylan 20 mg Gastro-resistant Capsules, hard	20 mg	Gastro-resistant capsule	Oral use
Ireland	McDermott Laboratories Ltd t/a Gerard Laboratories 35/36 Baldoye Industrial Estate Grange Road Dublin 13 Ireland	Esomeprazole	Esomeprazole Mylan 40 mg Gastro-resistant Capsules, hard	40 mg	Gastro-resistant capsule	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Ireland	McDermott Laboratories Ltd t/a Gerard Laboratories 35/36 Baldoyle Industrial Estate Grange Road Dublin 13 Ireland	Candesartan	Candesartan Mylan 4 mg Tablets	4 mg	Tablet	Oral use
Ireland	McDermott Laboratories Ltd t/a Gerard Laboratories 35/36 Baldoyle Industrial Estate Grange Road Dublin 13 Ireland	Candesartan	Candesartan Mylan 8 mg Tablets	8 mg	Tablet	Oral use
Ireland	McDermott Laboratories Ltd t/a Gerard Laboratories 35/36 Baldoyle Industrial Estate Grange Road Dublin 13 Ireland	Candesartan	Candesartan Mylan 16 mg Tablets	16 mg	Tablet	Oral use
Ireland	McDermott Laboratories Ltd t/a Gerard Laboratories 35/36 Baldoyle Industrial Estate Grange Road Dublin 13 Ireland	Candesartan	Candesartan Mylan 32 mg Tablets	32 mg	Tablet	Oral use
Ireland	Morningside Healthcare Limited 115 Narborough Road Leicester, LE3 0PA United Kingdom	Phenoxymethyl penicillin	Phenoxymethylpenicillin 250 mg Film-coated Tablets	250 mg	Film-coated tablet	Oral use
Ireland	Niche Generics Limited 1 The Cam Centre Wilbury Way, Hitchin Hertfordshire SG4 0TW United Kingdom	Amlodipine besilate	Amlodipine Niche 5 mg tablets	5 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Ireland	Niche Generics Limited 1 The Cam Centre Wilbury Way, Hitchin Hertfordshire SG4 0TW United Kingdom	Amlodipine besilate	Amlodipine Niche 10 mg Tablets	10 mg	Tablet	Oral use
Ireland	Niche Generics Limited 1 The Cam Centre Wilbury Way, Hitchin Hertfordshire SG4 0TW United Kingdom	Irbesartan	Irbesartan Niche 150 mg film-coated tablets	150 mg	Film-coated tablet	Oral use
Ireland	Niche Generics Limited 1 The Cam Centre Wilbury Way, Hitchin Hertfordshire SG4 0TW United Kingdom	Irbesartan	Irbesartan Niche 300 mg film-coated tablets	300 mg	Film-coated tablet	Oral use
Ireland	Wockhardt UK Limited Ash Road North Wrexham Industrial Estate Wrexham LL13 9UF United Kingdom	Clopidogrel hydrochloride	Clopidogrel 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral use
Italy	Accord Healthcare Italia S.r.l. Largo Esterle, 4 20052 Monza Italy	Metoclopramide	METOCLOPRAMIDE ACCORD	10 mg	Tablet	Oral use
Italy	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Alendronic acid	ALENDRONATO AHCL	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Italy	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Alendronic acid	ALENDRONATO AHCL	70 mg	Tablet	Oral use
Italy	Doc Generici SRL Via Turati, 40 20121 Milano Italy	Desloratadine	DESLOTATADINA DOC GENERICI	5 mg	Film-coated tablet	Oral use
Italy	Doc Generici SRL Via Turati, 40 20121 Milano Italy	Desloratadine	DESLOTATADINA DOC GENERICI	2,5 mg	Orodispersible tablet	Oral use
Italy	Doc Generici SRL Via Turati, 40 20121 Milano Italy	Desloratadine	DESLOTATADINA DOC GENERICI	5 mg	Orodispersible tablet	Oral use
Italy	Farmaceutici Caber S.P.A. Viale Citta' D'Europa, 681 00144 Rome Italy	Valsartan	VALSOTEN	40 mg	Film-coated tablet	Oral use
Italy	Farmaceutici Caber S.P.A. Viale Citta' D'Europa, 681 00144 Rome Italy	Valsartan	VALSOTEN	80 mg	Film-coated tablet	Oral use
Italy	Farmaceutici Caber S.P.A. Viale Citta' D'Europa, 681 00144 Rome Italy	Valsartan	VALSOTEN	160 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Italy	Farmaceutici Caber S.P.A. Viale Citta' D'Europa, 681 00144 Rome Italy	Valsartan	VALSOTEN	320 mg	Film-coated tablet	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Esomeprazole magnesium	ESOMEPRAZOLO MYLAN	20 mg	Gastro-resistant capsule, hard	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Esomeprazole magnesium	ESOMEPRAZOLO MYLAN	40 mg	Gastro-resistant capsule, hard	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Rizatriptan benzoate	RIAZATRIPTAN MYLAN GENERICS	5 mg	Orodispersible tablet	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Rizatriptan benzoate	RIAZATRIPTAN MYLAN GENERICS	10 mg	Orodispersible tablet	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Donepezil hydrochloride	DONEPEZIL MYLAN GENERICS ITALIA	5 mg	Orodispersible tablet	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Donepezil hydrochloride	DONEPEZIL MYLAN GENERICS ITALIA	10 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Repaglinide	REPAGLINIDE MYLAN	0,5 mg	Tablet	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Repaglinide	REPAGLINIDE MYLAN	1 mg	Tablet	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Repaglinide	REPAGLINIDE MYLAN	2 mg	Tablet	Oral use
Italy	Pensa Pharma S.P.A. Via Rossellini Ippolito, 12 20124 Milan Italy	Alendronic acid	Alendronato Pensa 70 mg compresse	70 mg	Tablet	Oral use
Italy	Ranbaxy Italia S.P.A. Piazza Filippo Meda, 4, 3 20121 — Milano Italy	Alendronic acid	ALENDRONATO RANBAXY ITA-LIA	70 mg	Tablet	Oral use
Latvia	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	Trimetazidine dihydrochloride	Zidmetin	35 mg	Modified-release tablet	Oral use
Lithuania	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Alendronic acid	Alendronic acid Accord	70 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Lithuania	Lambda Therapeutic Limited Sage House 319 Pinner Road, North Harrow Middlesex HA1 4HF United Kingdom	Ropinirole	Ropinirole Lambada	0,5 mg	Film-coated tablet	Oral use
Lithuania	Lambda Therapeutic Limited Sage House 319 Pinner Road, North Harrow Middlesex HA1 4HF United Kingdom	Ropinirole	Ropinirole Lambada	1 mg	Film-coated tablet	Oral use
Lithuania	Lambda Therapeutic Limited Sage House 319 Pinner Road, North Harrow Middlesex HA1 4HF United Kingdom	Ropinirole	Ropinirole Lambada	2 mg	Film-coated tablet	Oral use
Lithuania	Lambda Therapeutic Limited Sage House 319 Pinner Road, North Harrow Middlesex HA1 4HF United Kingdom	Ropinirole	Ropinirole Lambada	5 mg	Film-coated tablet	Oral use
Lithuania	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan	Irbesartanas Torrent	75 mg	Film-coated tablet	Oral use
Lithuania	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan	Irbesartanas Torrent	150 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Lithuania	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan	Irbesartanas Torrent	300 mg	Film-coated tablet	Oral use
Lithuania	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydrochlorothiazide	Irbesartanas/Hidrochlorotiazidas Torrent	150 mg/12,5 mg	Film-coated tablet	Oral use
Lithuania	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydrochlorothiazide	Irbesartanas/Hidrochlorotiazidas Torrent	300 mg/12,5 mg	Film-coated tablet	Oral use
Lithuania	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydrochlorothiazide	Irbesartanas/Hidrochlorotiazidas Torrent	300 mg/25 mg	Film-coated tablet	Oral use
Luxembourg	Mylan bvba/sprl Terhulpssteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan Pharma 0,5 mg tabletten	0,5 mg	Tablet	Oral use
Luxembourg	Mylan bvba/sprl Terhulpssteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan Pharma 1 mg tabletten	1 mg	Tablet	Oral use
Luxembourg	Mylan bvba/sprl Terhulpssteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan Pharma 2 mg tabletten	2 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Luxembourg	Mylan bvba/sprl Terhulpssteenweg 6A 1560 Hoeilaart Belgium	Esomeprazole	Esomeprazole Mylan	20 mg	Gastro-resistant capsule, hard	Oral use
Luxembourg	Mylan bvba/sprl Terhulpssteenweg 6A 1560 Hoeilaart Belgium	Esomeprazole	Esomeprazole Mylan	40 mg	Gastro-resistant capsule, hard	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan/hydrochlorothiazid 'Fair-Med' Coated tablets	160 mg/12,5 mg	Film-coated tablet	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan/hydrochlorothiazid 'Fair-Med' Coated tablets	320 mg/12,5 mg	Film-coated tablet	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan/hydrochlorothiazid 'Fair-Med' Coated tablets	320 mg/25 mg	Film-coated tablet	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Ciprofloxacin	Ciprofloxacin Fair-Med Coated Tablets	250 mg	Film-coated tablet	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Ciprofloxacin	Ciprofloxacin Fair-Med Coated Tablets	500 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	irbesartan	Irbesartan Fairmed 75 mg Film-coated Tablets	75 mg	Film-coated tablet	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	irbesartan	Irbesartan Fairmed 150 mg Film-coated Tablets	150 mg	Film-coated tablet	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	irbesartan	Irbesartan Fairmed 300 mg Film-coated Tablets	300 mg	Film-coated tablet	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan/Hydrochlorothiazide Fairmed 150 mg/12,5 mg film-coated tablets	150 mg/12,5 mg	Film-coated tablet	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan/Hydrochlorothiazide Fairmed 300 mg/12,5 mg film-coated tablets	300 mg/12,5 mg	Film-coated tablet	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan/Hydrochlorothiazide Fairmed 300 mg/25 mg film-coated tablets	300 mg/25 mg	Film-coated tablet	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Venlafaxine	Venlafaxine Fair-Med	37,5 mg	Prolonged — release capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Venlafaxine	Venlafaxine Fair-Med	75 mg	Prolonged — release capsule, hard	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Venlafaxine	Venlafaxine Fair-Med	150 mg	Prolonged — release capsule, hard	Oral use
Malta	Wockhardt UK Limited Ash Road North Wrexham Industrial Estate Wrexham LL13 9UF United Kingdom	Clopidogrel	Clopidogrel 75 mg Film-coated Tablets	75 mg	Film-coated tablet	Oral use
Malta	Wockhardt UK Limited Ash Road North Wrexham Industrial Estate Wrexham LL13 9UF United Kingdom	Clopidogrel	Clopidogrel 75 mg Coated Tablets	75 mg	Film-coated tablet	Oral use
Norway	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Fluconazole	Fluconazol Bluefish	50 mg	Capsule, hard	Oral use
Norway	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Fluconazole	Fluconazol Bluefish	150 mg	Capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Norway	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Fluconazole	Fluconazol Bluefish	200 mg	Capsule, hard	Oral use
Norway	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Esomeprazole	Esomeprazol Mylan	20 mg	Gastro-resistant capsule, hard	Oral use
Norway	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Esomeprazole	Esomeprazol Mylan	40 mg	Gastro-resistant capsule, hard	Oral use
Norway	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Eletriptan	Eletriptan Mylan	20 mg	Film-coated tablet	Oral use
Norway	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Eletriptan	Eletriptan Mylan	40 mg	Film-coated tablet	Oral use
Norway	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Candesartan cilexetil	Kandrozid	4 mg	tablet	Oral use
Norway	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Candesartan cilexetil	Kandrozid	8 mg	tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Norway	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Candesartan cilexetil	Kandrozid	16 mg	tablet	Oral use
Norway	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Candesartan cilexetil	Kandrozid	32 mg	tablet	Oral use
Norway	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Candesartan cilexetil	Mylcande	8 mg	tablet	Oral use
Norway	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Candesartan cilexetil	Mylcande	16 mg	tablet	Oral use
Norway	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Candesartan cilexetil	Mylcande	32 mg	tablet	Oral use
Norway	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Rizatriptan	RIZATRIPTAN MYLAN 10 mg, or- odispersible tablet	10 mg	Orodispersible tablet	Oral use
Norway	Ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm Germany	Desloratadine	Desloratadin Ratiopharm	2,5 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Norway	Ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm Germany	Desloratadine	Desloratadin Ratiopharm	5 mg	Orodispersible tablet	Oral use
Poland	Abbott Laboratories Poland Sp. z o.o. ul. Postępu 21B 02-676 Warszawa Poland	Escitalopram	Savandra	5 mg	Film-coated tablet	Oral use
Poland	Abbott Laboratories Poland Sp. z o.o. ul. Postępu 21B 02-676 Warszawa Poland	Escitalopram	Savandra	10 mg	Film-coated tablet	Oral use
Poland	Abbott Laboratories Poland Sp. z o.o. ul. Postępu 21B 02-676 Warszawa Poland	Escitalopram	Savandra	15 mg	Film-coated tablet	Oral use
Poland	Abbott Laboratories Poland Sp. z o.o. ul. Postępu 21B 02-676 Warszawa Poland	Escitalopram	Savandra	20 mg	Film-coated tablet	Oral use
Poland	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Metformin	Metformin SR Actavis	500 mg	Film-coated tablet	Oral use
Poland	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Metformin	Metformin SR Actavis	750 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Adamed Sp. z o.o. Pierków 149 05-152 Czosnów k. Warszawy Poland	Desloratadine	Desada	5 mg	Orodispersible tablet	Oral use
Poland	Adamed Sp. z o.o. Pierków 149 05-152 Czosnów k. Warszawy Poland	Desloratadine	Hitaxa Fast	2,5 mg	Orodispersible tablet	Oral use
Poland	Adamed Sp. z o.o. Pierków 149 05-152 Czosnów k. Warszawy Poland	Desloratadine	Hitaxa	2,5 mg	Orodispersible tablet	Oral use
Poland	Adamed Sp. z o.o. Pierków 149 05-152 Czosnów k. Warszawy Poland	Desloratadine	Hitaxa	5 mg	Orodispersible tablet	Oral use
Poland	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice Poland	Desloratadine	Teslor	5 mg	Film-coated tablet	Oral use
Poland	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice Poland	Desloratadine	Teslor fast	5 mg	Orodispersible tablet	Oral use
Poland	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice Poland	Desloratadine	Teslor fast junior	2,5 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Apotex Europe B.V. Darwinweg 20 NL 2333 CR Leiden Netherlands	Trimetazidine	ApoTrimet PR	35 mg	Prolonged — release tablet	Oral use
Poland	Bio-Profil Polska Sp. z o.o. Trakt Lubelski 135 04-790 Warszawa Poland	Desloratadine	Desloratadine Peseri	5 mg	Film-coated tablet	Oral use
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan HCT Fair-Med	320 mg/12,5 mg	Film-coated tablet	Oral use
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan HCT Fair-Med	320 mg/25 mg	Film-coated tablet	Oral use
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Ciprofloxacin	Ciprofloxacin Fair-Med	250 mg	Film-coated tablet	Oral use
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Ciprofloxacin	Ciprofloxacin Fair-Med	500 mg	Film-coated tablet	Oral use
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan	Irbesartan Fair-Med	75 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan	Irbesartan Fair-Med	150 mg	Film-coated tablet	Oral use
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan	Irbesartan Fair-Med	300 mg	Film-coated tablet	Oral use
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan HCT Fair-Med	150 mg/12,5 mg	Film-coated tablet	Oral use
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan HCT Fair-Med	300 mg/12,5 mg	Film-coated tablet	Oral use
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan HCT Fair-Med	300 mg/25 mg	Film-coated tablet	Oral use
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochlorothiazide	Valsartan HCT Fair-Med	160 mg/12,5 mg	Film-coated tablet	Oral use
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Venlafaxine	VENLAFAXINE FAIR-MED	37,5 mg	Prolonged — release capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Venlafaxine	VENLAFAXINE FAIR-MED	75 mg	Prolonged — release capsule, hard	Oral use
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Venlafaxine	VENLAFAXINE FAIR-MED	150 mg	Prolonged — release capsule, hard	Oral use
Poland	Generics (UK) Ltd Station Close, Porters Bar Hertfordshire, EN6 1TL United Kingdom	Candesartan cilexetil	Kangen	8 mg	Tablet	Oral use
Poland	Generics (UK) Ltd Station Close, Porters Bar Hertfordshire, EN6 1TL United Kingdom	Candesartan cilexetil	Kangen	16 mg	Tablet	Oral use
Poland	Labormed-Pharma, SA Theodor Pallady, 44B 032266 Bucharest Romania	Desloratadine	Desloratadine Labormed	2,5 mg	Orodispersible tablet	Oral use
Poland	Labormed-Pharma, SA Theodor Pallady, 44B 032266 Bucharest Romania	Desloratadine	Desloratadine Labormed	5 mg	Orodispersible tablet	Oral use
Poland	Medicplast Polska Sp. z o.o ul. Wólczyńska 232 01-919 Warszawa Poland	Desloratadine	Desalergo	5 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Medicplast Polska Sp. z o.o ul. Wólczyńska 232 01-919 Warszawa Poland	Desloratadine	Desalergo	2,5 mg	Orodispersible tablet	Oral use
Poland	Medicplast Polska Sp. z o.o ul. Wólczyńska 232 01-919 Warszawa Poland	Desloratadine	Desalergo	5 mg	Orodispersible tablet	Oral use
Poland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	Valsartan Orion	40 mg	Film-coated tablet	Oral use
Poland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	Valsartan Orion	80 mg	Film-coated tablet	Oral use
Poland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	Valsartan Orion	160 mg	Film-coated tablet	Oral use
Poland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	Valsartan Orion	320 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Peseri Trading Limited 20 Queen Frederica Street El-Greco House, office 301 1066 Nicosia Cyprus	Desloratadine	Desloratadine Peseri	2,5 mg	Orodispersible tablet	Oral use
Poland	Peseri Trading Limited 20 Queen Frederica Street El-Greco House, office 301 1066 Nicosia Cyprus	Desloratadine	Desloratadine Peseri	5 mg	Orodispersible tablet	Oral use
Poland	Ranbaxy (Poland) Sp. z o.o. Kubickiego 11 02-954 Warszawa Poland	Alendronic acid	Alendran 70	70 mg	Tablet	Oral use
Poland	Sandoz GmbH Biochemiestrasse 10 A-6250 Kundl Austria	Trimetazidine	Dimesar	35 mg	Prolonged — release tablet	Oral use
Poland	S-Lab Sp. z o.o. ul. Kielczowska 2 55-095 Mirków Poland	Desloratadine	Suprodeslon	5 mg	Film-coated tablet	Oral use
Poland	S-Lab Sp. z o.o. ul. Kielczowska 2 55-095 Mirków Poland	Desloratadine	Suprodeslon	2,5 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	S-Lab Sp. z o.o. ul. Kielczowska 2 55-095 Mirków Poland	Desloratadine	Suprodeslon	5 mg	Orodispersible tablet	Oral use
Poland	SymPhar Sp. z o.o. ul. Włoska 1 00-777 Warszawa Poland	Desloratadine	Symdes	5 mg	Film-coated tablet	Oral use
Poland	Tactica Pharmaceuticals sp. z o.o. ul. Bankowa 4 44-100 Gliwice Poland	Desloratadine	Goldesin	5 mg	Film-coated tablet	Oral use
Poland	US Pharmacia Sp. z o.o. ul. Ziębicka 40 50-507 Wrocław Poland	Desloratadine	Aleric Deslo	5 mg	Film-coated tablet	Oral use
Poland	US Pharmacia Sp. z o.o. ul. Ziębicka 40 50-507 Wrocław Poland	Desloratadine	Aleric Deslo	2,5 mg	Orodispersible tablet	Oral use
Poland	US Pharmacia Sp. z o.o. ul. Ziębicka 40 50-507 Wrocław Poland	Desloratadine	Aleric Deslo Active	5 mg	Orodispersible tablet	Oral use
Poland	Wockhardt UK Limited Ash Road North Wrexham Industrial Estate Wrexham LL13 9UF United Kingdom	Clopidogrel	Clopidogrel Wockhardt	75 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Alendronic acid	Ácido alendrónico Accord	70 mg	tablet	Oral use
Portugal	Alkaloid — INT d.o.o. Šlandrova 4 1231 Ljubljana — Črnuče Slovenia	Cefpodoxime	Cefpodoxima Alkaloid	200 mg	Tablet	Oral use
Portugal	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Tramadol/paracetamol	Tramadol + Paracetamol Brown	37,5 mg/325 mg	Film-coated tablet	Oral use
Portugal	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Trimetazidine	Trimetazidina Brown	35 mg	Modified-release tablet	Oral use
Portugal	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram	Escitalopram Brown	10 mg	Film-coated tablet	Oral use
Portugal	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram	Escitalopram Brown	15 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram	Escitalopram Brown	5 mg	Film-coated tablet	Oral use
Portugal	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram	Escitalopram Brown	20 mg	Film-coated tablet	Oral use
Portugal	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Ebastine	Ebastina Brown	10 mg	Film-coated tablet	Oral use
Portugal	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Ebastine	Ebastina Brown	20 mg	Film-coated tablet	Oral use
Portugal	Daquimed — Comércio de Produtos Farmacêuticos, S.A. Av. Associação Comercial e Industrial de Gondomar, 330 — Zona Industrial da Portelinha 4510-688 Fânzeres Portugal	Quetiapine	Quetiapina Daquimed	25 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Daquimed — Comércio de Produtos Farmacêuticos, S.A. Av. Associação Comercial e Industrial de Gondomar, 330 — Zona Industrial da Portelinha 4510-688 Fânzeres Portugal	Quetiapine	Quetiapina Daquimed	100 mg	Film-coated tablet	Oral use
Portugal	Daquimed — Comércio de Produtos Farmacêuticos, S.A. Av. Associação Comercial e Industrial de Gondomar, 330 — Zona Industrial da Portelinha 4510-688 Fânzeres Portugal	Quetiapine	Quetiapina Daquimed	150 mg	Film-coated tablet	Oral use
Portugal	Daquimed — Comércio de Produtos Farmacêuticos, S.A. Av. Associação Comercial e Industrial de Gondomar, 330 — Zona Industrial da Portelinha 4510-688 Fânzeres Portugal	Quetiapine	Quetiapina Daquimed	200 mg	Film-coated tablet	Oral use
Portugal	Daquimed — Comércio de Produtos Farmacêuticos, S.A. Av. Associação Comercial e Industrial de Gondomar, 330 — Zona Industrial da Portelinha 4510-688 Fânzeres Portugal	Quetiapine	Quetiapina Daquimed	300 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Levodopa/carbidopa/ entacapone	Levodopa + Carbidopa + Entacapona Generis	50 mg/12,5 mg/ 200 mg	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Levodopa/carbidopa/ entacapone	Levodopa + Carbidopa + Entacapona Generis	75 mg/ 18,75 mg/ 200 mg	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Levodopa/carbidopa/ entacapone	Levodopa + Carbidopa + Entacapona Generis	100 mg/25 mg/ 200 mg	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Levodopa/carbidopa/ entacapone	Levodopa + Carbidopa + Entacapona Generis	125 mg/ 31,250 mg/ 200 mg	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Levodopa/carbidopa/ entacapone	Levodopa + Carbidopa + Entacapona Generis	150 mg/ 37,5 mg/200 mg	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Levodopa/carbidopa/ entacapone	Levodopa + Carbidopa + Entacapona Generis	175 mg/ 43,75 mg/ 200 mg	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Levodopa/carbidopa/ entacapone	Levodopa + Carbidopa + Entacapona Generis	200 mg/50 mg/ 200 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Entacapone	Entacapona Generis	200 mg	Film-coated tablet	Oral use
Portugal	Labesfal, Genéricos, S.A. Av. Dr Afonso Costa, n.º 1370 3465-051 Campo de Besteiros Portugal	Desloratadine	Desloratadina Labesfal OD	2,5 mg	Orodispersible tablet	Oral use
Portugal	Labesfal, Genéricos, S.A. Av. Dr Afonso Costa, n.º 1370 3465-051 Campo de Besteiros Portugal	Desloratadine	Desloratadina Labesfal OD	5 mg	Orodispersible tablet	Oral use
Portugal	Labesfal, Genéricos, S.A. Av. Dr Afonso Costa, n.º 1370 3465-051 Campo de Besteiros Portugal	Alendronic acid	Ácido alendrónico Labesfal	70 mg	tablet	Oral use
Portugal	Laboratórios Anova — Produtos Farmacêuticos, Lda. Rua Doutor António Loureiro Borges Edifício Arquiparque 1, R/C Esq.º 1499-016 Algés Portugal	Donepezil	Donepezilo Anova	5 mg	Orodispersible tablet	Oral use
Portugal	Laboratórios Anova — Produtos Farmacêuticos, Lda. Rua Doutor António Loureiro Borges Edifício Arquiparque 1, R/C Esq.º 1499-016 Algés Portugal	Donepezil	Donepezilo Anova	10 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Laboratórios Anova — Produtos Farmacêuticos, Lda. Rua Doutor António Loureiro Borges Edifício Arquiparque 1, R/C Esqº 1499-016 Algés Portugal	Esomeprazole	Esomeprazol Anova	20 mg	Gastro-resistant capsule, hard	Oral use
Portugal	Laboratórios Anova — Produtos Farmacêuticos, Lda. Rua Doutor António Loureiro Borges Edifício Arquiparque 1, R/C Esqº 1499-016 Algés Portugal	Esomeprazole	Esomeprazol Anova	40 mg	Gastro-resistant capsule, hard	Oral use
Portugal	Laboratórios Azevedos — Indústria Farmacêutica, S.A. Edifícios Azevedos — Estrada Nacional 117-2, Alfragide 2614-504 Amadora Portugal	Venlafaxine	Venlafaxina Azevedos	37,5 mg	Prolonged — release capsule, hard	Oral use
Portugal	Laboratórios Azevedos — Indústria Farmacêutica, S.A. Edifícios Azevedos — Estrada Nacional 117-2, Alfragide 2614-504 Amadora Portugal	Venlafaxine	Venlafaxina Azevedos	75 mg	Prolonged — release capsule, hard	Oral use
Portugal	Laboratórios Azevedos — Indústria Farmacêutica, S.A. Edifícios Azevedos — Estrada Nacional 117-2, Alfragide 2614-504 Amadora Portugal	Venlafaxine	Venlafaxina Azevedos	150 mg	Prolonged — release capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Laboratórios Basi — Indústria Farmacêutica, S.A Parque Industrial Manuel Lourenço Ferreira, Lote 15 3450-232 Mortágua Portugal	Fluconazole	Fluconazol Basi	50 mg	Capsule	Oral use
Portugal	Laboratórios Basi — Indústria Farmacêutica, S.A Parque Industrial Manuel Lourenço Ferreira, Lote 15 3450-232 Mortágua Portugal	Fluconazole	Fluconazol Basi	150 mg	Capsule	Oral use
Portugal	Laboratórios Basi — Indústria Farmacêutica, S.A Parque Industrial Manuel Lourenço Ferreira, Lote 15 3450-232 Mortágua Portugal	Fluconazole	Fluconazol Basi	200 mg	Capsule	Oral use
Portugal	Labormed-Pharma, SA Theodor Pallady, 44B 032266 Bucharest Romania	Desloratadine	Desloratadina Labormed	5 mg	Orodispersible tablet	Oral use
Portugal	Labormed-Pharma, SA Theodor Pallady, 44B 032266 Bucharest Romania	Desloratadine	Desloratadina Labormed	2,5 mg	Orodispersible tablet	Oral use
Portugal	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 0PF United Kingdom	Cefpodoxime	Cefpodoxima Lupin	200 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Esomeprazole	Esomeprazol Mylan	20 mg	Gastro-resistant capsule, hard	Oral use
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Esomeprazole	Esomeprazol Mylan	40 mg	Gastro-resistant capsule, hard	Oral use
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Atorvastatin	Atorvastatina Anova	10 mg	Film-coated tablet	Oral use
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Atorvastatin	Atorvastatina Anova	20 mg	Film-coated tablet	Oral use
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Atorvastatin	Atorvastatina Anova	40 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Atorvastatin	Atorvastatina Anova	80 mg	Film-coated tablet	Oral use
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Donepezil	Donepezilo Mylan	5 mg	Orodispersible tablet	Oral use
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Donepezil	Donepezilo Mylan	10 mg	Orodispersible tablet	Oral use
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Trimetazidine	Trimetazidina Mylan	35 mg	Modified-release tablet	Oral use
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Candesartan	Candesartan Mylan	4 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Candesartan	Candesartan Mylan	8 mg	Tablet	Oral use
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Candesartan	Candesartan Mylan	16 mg	Tablet	Oral use
Portugal	Mylan, Lda. Parque Expo, Edifício Atlantis, Avenida D. João II, Lote 1.06.2.2 C - 7.3 e 7.4 1990-095 Lisboa Portugal	Candesartan	Candesartan Mylan	32 mg	Tablet	Oral use
Portugal	Peseri Trading Limited 20 Queen Frederica Street El-Greco House, office 301 1066 Nicosia Cyprus	Desloratadine	Desloratadina Peseri	5 mg	Film-coated tablet	Oral use
Portugal	Peseri Trading Limited 20 Queen Frederica Street El-Greco House, office 301 1066 Nicosia Cyprus	Desloratadine	Desloratadina Peseri	5 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Peseri Trading Limited 20 Queen Frederica Street El-Greco House, office 301 1066 Nicosia Cyprus	Desloratadine	Desloratadina Peseri	2,5 mg	Orodispersible tablet	Oral use
Portugal	Pharmakern Portugal — Produtos Farmacêuticos, Sociedade Unipessoal, Lda. Edifício Atlas II, Av. José Gomes Ferreira, N.º 11 — 3.º, Sala 31 — Miraflores 1495-139 Algés Portugal	Trimetazidine	Trimetazidina Pharmakern	35 mg	Modified-release tablet	Oral use
Portugal	Ratiopharm — Comércio e Indústria de Produtos Farmacêuticos, Lda. Lagoas Park, Edifício 5 A, Piso 2 2740-245 Porto Salvo Portugal	Desloratadine	Desloratadina Ratiopharm	2,5 mg	Orodispersible tablet	Oral use
Portugal	Ratiopharm — Comércio e Indústria de Produtos Farmacêuticos, Lda. Lagoas Park, Edifício 5 A, Piso 2 2740-245 Porto Salvo Portugal	Desloratadine	Desloratadina Ratiopharm	5 mg	Orodispersible tablet	Oral use
Portugal	Sandoz Farmaceutica Lda. Avenida Professor Doutor Cavaco Silva, n. 10E Taguspark 2740-255 Porto Salvo Portugal	Trimetazidine	Trimetazidina Itraxel	35 mg	Prolonged — release tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Teva Pharma — Produtos Farmacêuticos, Lda. Edifício Tejo, Rua Quinta do Pinheiro, 16 — 6.º 2790-143 Carnaxide Portugal	Desloratadine	Desloratadina Teva	2,5 mg	Orodispersible tablet	Oral use
Portugal	Teva Pharma — Produtos Farmacêuticos, Lda. Edifício Tejo, Rua Quinta do Pinheiro, 16 — 6.º 2790-143 Carnaxide Portugal	Desloratadine	Desloratadina Teva	5 mg	Orodispersible tablet	Oral use
Romania	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	SAVANDRA 5 mg comprimate filmate	5 mg	Film-coated tablet	Oral use
Romania	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	SAVANDRA 10 mg comprimate filmate	10 mg	Film-coated tablet	Oral use
Romania	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	SAVANDRA 15 mg comprimate filmate	15 mg	Film-coated tablet	Oral use
Romania	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	SAVANDRA 20 mg comprimate filmate	20 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Romania	Alkaloid — INT d.o.o. Šlandrova 4 1231 Ljubljana — Črnuče Slovenia	Cefpodoxime	Forexo 200 mg comprimate filmate	200 mg	Tablet	Oral use
Romania	Alvogen IPCo S.ar.l. Rue Heienhaff 5 L-1736 Senningerberg Luxembourg	Desloratadine	Desloratadina Alvogen 5 mg comprimate filmate	5 mg	Film-coated tablet	Oral use
Romania	Dr Reddy's Laboratories Romania SRL 71st-73rd Nicolae Caramfil, Floor 5, Space 10, Sector 1, Bucuresti, Romania	Levetiracetam	Levetiracetam Dr Reddy's, 250 mg, comprimate filmate	250 mg	Tablet	Oral use
Romania	Dr Reddy's Laboratories Romania SRL 71st-73rd Nicolae Caramfil, Floor 5, Space 10, Sector 1, Bucuresti, Romania	Levetiracetam	Levetiracetam Dr Reddy's, 500 mg, comprimate filmate	500 mg	Tablet	Oral use
Romania	Dr Reddy's Laboratories Romania SRL 71st-73rd Nicolae Caramfil, Floor 5, Space 10, Sector 1, Bucuresti, Romania	Levetiracetam	Levetiracetam Dr Reddy's, 750 mg, comprimate filmate	750 mg	Tablet	Oral use
Romania	Dr Reddy's Laboratories Romania SRL 71st-73rd Nicolae Caramfil, Floor 5, Space 10, Sector 1, Bucuresti, Romania	Levetiracetam	Levetiracetam Dr Reddy's, 1 000 mg, comprimate filmate	1 000 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Romania	Dr Reddy's Laboratories Romania SRL 71st-73rd Nicolae Caramfil, Floor 5, Space 10, Sector 1, Bucuresti, Romania	Telmisartan	Telmisartan Dr Reddy's 40 mg comprimate	40 mg	Tablet	Oral use
Romania	Dr Reddy's Laboratories Romania SRL 71st-73rd Nicolae Caramfil, Floor 5, Space 10, Sector 1, Bucuresti, Romania	Telmisartan	Telmisartan Dr Reddy's 80 mg comprimate	80 mg	Tablet	Oral use
Romania	Dr Reddy's Laboratories Romania SRL 71st-73rd Nicolae Caramfil, Floor 5, Space 10, Sector 1, Bucuresti, Romania	Telmisartan/ hydrochlorothiazide	Telmisartan HCT Dr Reddy's 40 mg/ 12,5 mg comprimate	40 mg/12,5 mg	Tablet	Oral use
Romania	Dr Reddy's Laboratories Romania SRL 71st-73rd Nicolae Caramfil, Floor 5, Space 10, Sector 1, Bucuresti, Romania	Telmisartan/ hydrochlorothiazide	Telmisartan HCT Dr Reddy's 80 mg/ 12,5 mg comprimate	80 mg/12,5 mg	Tablet	Oral use
Romania	Dr Reddy's Laboratories Romania SRL 71st-73rd Nicolae Caramfil, Floor 5, Space 10, Sector 1, Bucuresti, Romania	Telmisartan/ hydrochlorothiazide	Telmisartan HCT Dr Reddy's 80 mg/ 25 mg comprimate	80 mg/25 mg	Tablet	Oral use
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Esomeprazole magne- sium	Esomeprazol Mylan 20 mg capsule gastrorezistente	20 mg	Gastro-resistant cap- sule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Esomeprazole magnesium	Esomeprazol Mylan 40 mg capsule gastrorezistente	40 mg	Gastro-resistant capsule, hard	Oral use
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Donepezil hydrochloride	Donepezil Mylan 5 mg comprimate orodispersabile	5 mg	Orodispersible tablet	Oral use
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Donepezil hydrochloride	Donepezil Mylan 10 mg comprimate orodispersabile	10 mg	Orodispersible tablet	Oral use
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Repaglinide	Repaglinida Generics 0,5 mg comprimate	0,5 mg	Tablet	Oral use
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Repaglinide	Repaglinida Generics 1 mg comprimate	1 mg	Tablet	Oral use
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Repaglinide	Repaglinida Generics 2 mg comprimate	2 mg	Tablet	Oral use
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Candesartan cilexetil	Candesartan Mylan 4 mg comprimate	4 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Candesartan cilexetil	Candesartan Mylan 8 mg comprimate	8 mg	Tablet	Oral use
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Candesartan cilexetil	Candesartan Mylan 16 mg comprimate	16 mg	Tablet	Oral use
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Rizatriptan benzoate	Rizatriptan Mylan 5 mg comprimate orodispersabile	5 mg	Orodispersible tablet	Oral use
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Rizatriptan benzoate	Rizatriptan Mylan 10 mg comprimate orodispersabile	10 mg	Orodispersible tablet	Oral use
Romania	Glenmark Pharmaceuticals s.r.o. Hvězdova 1716/2b 14078 Praha 4 Czech Republic	Trimetazidine	Apstar 35 mg Comprimare cu eliberare prelungită	35 mg	Modified-release tablet	Oral use
Romania	Labormed Pharma SA Bd. Theodor Pallady nr. 44 B 032266, sector 3, București România	Desloratadine	Desloratadine Labormed 2,5 mg comprimate orodispersabile	2,5 mg	Orodispersible tablet	Oral use
Romania	Labormed Pharma SA Bd. Theodor Pallady nr. 44 B 032266, sector 3, București România	Desloratadine	Desloratadine Labormed 5 mg comprimate orodispersabile	5 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Romania	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Trimetazidine	Trimetazidina Mylan 35 mg comprimate filmate cu eliberare prelungita	35 mg	Prolonged — release tablet	Oral use
Romania	Sandoz Pharma Services SRL Calea Floreasca Street No 169A, district 2 Bucharest Romania	Trimetazidine	Trimeluzine Limited 35 mg comprimate filmate cu eliberare modificata	35 mg	Modified-release tablet	Oral use
Romania	STADA Hemofarm S.R.L. Calea Torontalului km 6 — PITT 300633 Timișoara Romania	Entacapone	ENTANIDA 200 comprimate filmate	200 mg	Film-coated tablet	Oral use
Romania	Teva Pharmaceuticals S.R.L. Str. Domnița Ruxandra nr. 12, parter, sector 2, București, România	Desloratadine	Desloratadina Teva 5 mg comprimate orodispersabile	5 mg	Orodispersible tablet	Oral use
Romania	Torrent Pharma SRL Str. Stirbei Voda nr. 36 et. 2, biroul A, sector 1 Bucharest Romania	Irbesartan	Irbesartan Torrent 75 mg comprimate filmate	75 mg	Film-coated tablet	Oral use
Romania	Torrent Pharma SRL Str. Stirbei Voda nr. 36 et. 2, biroul A, sector 1 Bucharest Romania	Irbesartan	Irbesartan Torrent 150 mg comprimate filmate	150 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Romania	Torrent Pharma SRL Str. Stirbei Voda nr. 36 et. 2, biroul A, sector 1 Bucharest Romania	Irbesartan	Irbesartan Torrent 300 mg comprimate filmate	300 mg	Film-coated tablet	Oral use
Romania	Torrent Pharma SRL Str. Stirbei Voda nr. 36 et. 2, biroul A, sector 1 Bucharest Romania	Irbesartan/hydrochlorothiazide	Irbesartan Torrent Hidrochlorotiazida 150/12,5 mg comprimate filmate	150 mg/12,5 mg	Film-coated tablet	Oral use
Romania	Torrent Pharma SRL Str. Stirbei Voda nr. 36 et. 2, biroul A, sector 1 Bucharest Romania	Irbesartan/hydrochlorothiazide	Irbesartan Torrent Hidrochlorotiazida 300/12,5 mg comprimate filmate	300 mg/12,5 mg	Film-coated tablet	Oral use
Romania	Torrent Pharma SRL Str. Stirbei Voda nr. 36 et. 2, biroul A, sector 1 Bucharest Romania	Irbesartan/hydrochlorothiazide	Irbesartan Torrent Hidrochlorotiazida 300/25 mg comprimate filmate	300 mg/25 mg	Film-coated tablet	Oral use
Slovak Republic	Alkaloid — INT d.o.o. Šlandrova 4 1231 Ljubljana — Črnuče Slovenia	Cefpodoxime	FOREXO 200 mg filmom obalené tablety	200 mg	Film-coated tablet	Oral use
Slovak Republic	Alvogen IPCo S.à.r.l. Rue Heienhaff 5 L-1736 Senningerberg Luxembourg	Desloratadine	Dezloratadin Alvogen 5 mg filmom obalené tablety	5 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Slovak Republic	Genericon s.r.o., Anny Letenské 1108/15, 120 00 Praha 2 — Vinohrady Czech Republic	Desloratadine	GESLORA 5 mg	5 mg	Film-coated tablet	Oral use
Slovak Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Donepezil hydrochloride	Donepezil Mylan 5 mg orodispersgovatel'né tablety	5 mg	Orodispersible tablet	Oral use
Slovak Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Donepezil hydrochloride	Donepezil Mylan 10 mg orodispersgovatel'né tablety	10 mg	Orodispersible tablet	Oral use
Slovak Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Rizatriptan benzoate	Rizatriptan Mylan 10 mg	10 mg	Orodispersible tablet	Oral use
Slovak Republic	Glenmark Pharmaceuticals s.r.o. Hvězdova 1716/2b 14078 Praha 4 Czech Republic	Trimetazidine	Apstar 35 mg tablety s predlženým uvolňováním	35 mg	Modified-release tablet	Oral use
Slovak Republic	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Trimetazidine	Trimetazidin Mylan 35 mg	35 mg	Modified-release tablet	Oral use
Slovak Republic	SVUS Pharma a.s. Smetanovo nábřeží 1238/20a 500 02 Hradec Králové Czech Republic	Desloratadine	LOTERA 5 mg filmom obalené tablety	5 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Slovak Republic	Teva Pharmaceuticals Slovakia s.r.o. Teslova 26 821 02 Bratislava Slovak Republic	Desloratadine	Dezloratadin Teva OROTAB 2,5 mg	2,5 mg	Orodispersible tablet	Oral use
Slovak Republic	Teva Pharmaceuticals Slovakia s.r.o. Teslova 26 821 02 Bratislava Slovak Republic	Desloratadine	Dezloratadin Teva OROTAB 5 mg	5 mg	Orodispersible tablet	Oral use
Slovenia	Alkaloid — INT d.o.o. Šlandrova 4 1231 Ljubljana — Črnuče Slovenia	Cefpodoxime	Trexodo 200 mg filmsko obložene tablete	200 mg	Film-coated tablet	Oral use
Slovenia	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Esomeprazole magnesium	Esomeprazol Mylan 20 mg trde gastrorezištentne kapsule	20 mg	Gastro-resistant capsule, hard	Oral use
Slovenia	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Esomeprazole magnesium	Esomeprazol Mylan 40 mg trde gastrorezištentne kapsule	40 mg	Gastro-resistant capsule, hard	Oral use
Slovenia	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Donepezil hydrochloride	Donepezil Mylan 5 mg orodispersibilne tablete	5 mg	Orodispersible tablet	Oral use
Slovenia	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Donepezil hydrochloride	Donepezil Mylan 10 mg orodispersibilne tablete	10 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Slovenia	Lek farmacevtska družba d.d. Verovškova 57 1526 Ljubljana Slovenia	Trimetazidine hydrochloride	Trimeluzine 35 mg tablete s podaljšanim sproščanjem	35 mg	Prolonged — release tablet	Oral use
Spain	Accord Healthcare, S.L.U. Moll de Barcelona s/n. World Trade Center. Edifici Est 6 ^a planta, 8039 Barcelona Spain	Metoclopramide	METOCLOPRAMIDA ACCORD 10 mg COMPRIMIDOS EFG	10 mg	Tablet	Oral use
Spain	Apotex Europe B.V. Darwinweg 20 NL 2333 CR Leiden Netherlands	Desloratadine	DESLOTATADINA APOTEX 5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	5 mg	Film-coated tablet	Oral use
Spain	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Ebastine	EBASTINA BROWN 10 mg COMPRIMIDOS BUCODISPERSABLES EFG	10 mg	Orodispersible tablet	Oral use
Spain	Farmalider, S.A. Aragoneses 15 28108 Madrid Spain	Valsartan/hydrochlorothiazide	VALSARTAN/HIDROCLOROTIAZIDA CODRAMOL 160 MG/12,5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	160 mg/12,5 mg	Film-coated tablet	Oral use
Spain	Farmalider, S.A. Aragoneses 15 28108 Madrid Spain	Valsartan/hydrochlorothiazide	VALSARTAN/HIDROCLOROTIAZIDA CODRAMOL 160/25 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	160 mg/25 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	Farmalider, S.A. Aragoneses 15 28108 Madrid Spain	Valsartan/hydrochlorothiazide	VALSARTAN/HIDROCLOROTIAZIDA CODRAMOL 320/12,5 mg COMPRIMIDOS RECUBIERTOS CON PELÍCULA EFG	320 mg/12,5 mg	Film-coated tablet	Oral use
Spain	Farmalider, S.A. Aragoneses 15 28108 Madrid Spain	Valsartan/hydrochlorothiazide	VALSARTAN/HIDROCLOROTIAZIDA CODRAMOL 320/25 mg COMPRIMIDOS RECUBIERTOS CON PELÍCULA EFG	320 mg/25 mg	Film-coated tablet	Oral use
Spain	Farmalider, S.A. Aragoneses 15 28108 Madrid Spain	Valsartan/hydrochlorothiazide	VALSARTAN/HIDROCLOROTIAZIDA CODRAMOL 80/12,5 mg COMPRIMIDOS RECUBIERTOS CON PELÍCULA EFG	80 mg/12,5 mg	Film-coated tablet	Oral use
Spain	Laboratorios Combix, S.L.U. C/Badajoz 2, Edificio 2 Pozuelo de Alarcon Madrid 28223 Spain	Desloratadine	DESLOTATADINA COMBIX 5 mg COMPRIMIDOS RECUBIERTOS CON PELÍCULA EFG	5 mg	Film-coated tablet	Oral use
Spain	Laboratorios Combix, S.L.U. C/Badajoz 2, Edificio 2 Pozuelo de Alarcon Madrid 28223 Spain	Desloratadine	DESLOTATADINA FLAS COMBIX 5 mg COMPRIMIDOS BUCODISPERSABLES EFG	5 mg	Film-coated tablet	Oral use
Spain	Laboratorios Combix, S.L.U. C/Badajoz 2, Edificio 2 Pozuelo de Alarcon Madrid 28223 Spain	Escitalopram	ESCITALOPRAM COMBIX 10 mg COMPRIMIDOS RECUBIERTOS CON PELÍCULA EFG	10 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	Laboratorios Combix, S.L.U. C/Badajoz 2, Edificio 2 Pozuelo de Alarcon Madrid 28223 Spain	Escitalopram	ESCITALOPRAM COMBIX 15 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	15 mg	Film-coated tablet	Oral use
Spain	Laboratorios Combix, S.L.U. C/Badajoz 2, Edificio 2 Pozuelo de Alarcon Madrid 28223 Spain	Escitalopram	ESCITALOPRAM COMBIX 20 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	20 mg	Film-coated tablet	Oral use
Spain	Laboratorios Combix, S.L.U. C/Badajoz 2, Edificio 2 Pozuelo de Alarcon Madrid 28223 Spain	Escitalopram	ESCITALOPRAM COMBIX 5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	5 mg	Film-coated tablet	Oral use
Spain	Laboratorios Ranbaxy, S. L. U. Paseig de Gracia 9 7a Pl Barcelona 08007 Spain	Alendronic acid	ACIDO ALENDRONICO SEMANAL RANBAXY 70 mg COMPRIMIDOS EFG	70 mg	Tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L. Plom 2-4, 5º Planta 8038 Barcelona Spain	Donepezil	DONEPEZILO FLAS MYLAN PHARMACEUTICALS 10 mg COMPRIMIDOS BUCODISPERSA- BLES EFG	10 mg	Orodispersible tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L. Plom 2-4, 5º Planta 8038 Barcelona Spain	Donepezil	DONEPEZILO FLAS MYLAN PHARMACEUTICALS 5 mg COM- PRIMIDOS BUCODISPERSABLES EFG	5 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	Mylan Pharmaceuticals, S.L. Plom 2-4, 5° Planta 8038 Barcelona Spain	Esomeprazole	ESOMEPRAZOL MYLAN 20 mg CAPSULAS GASTORRESIS- TENTES EFG	20 mg	Gastro-resistant cap- sule	Oral use
Spain	Mylan Pharmaceuticals, S.L. Plom 2-4, 5° Planta 8038 Barcelona Spain	Esomeprazole	ESOMEPRAZOL MYLAN 40 mg CAPSULAS GASTORRESIS- TENTES EFG	40 mg	Gastro-resistant cap- sule	Oral use
Spain	Mylan Pharmaceuticals, S.L. Plom 2-4, 5° Planta 8038 Barcelona Spain	Repaglinide	REPAGLINIDA MYLAN 0,5 mg COMPRIMIDOS EFG	0,5 mg	Tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L. Plom 2-4, 5° Planta 8038 Barcelona Spain	Repaglinide	REPAGLINIDA MYLAN 1 mg COMPRIMIDOS EFG	1 mg	Tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L. Plom 2-4, 5° Planta 8038 Barcelona Spain	Repaglinide	REPAGLINIDA MYLAN 2 mg COMPRIMIDOS EFG	2 mg	Tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L. Plom 2-4, 5° Planta 8038 Barcelona Spain	Rizatriptan	RIZATRIPTAN MAX MYLAN 10 mg COMPRIMIDOS BUCODIS- PERSABLES EFG	10 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	PENSA PHARMA, S.A.U Jorge Comín (médico pediatra) 3 — bajos 46015 – Valencia (Valencia) Spain	Alendronic acid	ACIDO ALENDRONICO SEMANAL PENSA 70 mg COMPRIMIDOS EFG	70 mg	Tablet	Oral use
Spain	Pharmagenus, S.A., Avda. Camí Real, 51-57, 08184 Palau-solita i Plegamans (Barce- lona) Spain	Desloratadine	DESLOTATADINA PHARMA- GENUS 2,5 mg COMPRIMIDOS BUCODISPERSABLES EFG	2,5 mg	Orodispersible tablet	Oral use
Spain	Pharmagenus, S.A., Avda. Camí Real, 51-57, 08184 Palau-solita i Plegamans (Barce- lona) Spain	Desloratadine	DESLOTATADINA PHARMA- GENUS 5 mg COMPRIMIDOS BU- CODISPERSABLES EFG	5 mg	Orodispersible tablet	Oral use
Spain	Teva Pharma S.L.U. C/Anabel Segura, 11 Edificio Albatros B, 1ª planta Madrid 28108 Spain	Desloratadine	DESLOTATADINA TEVA 5 mg COMPRIMIDOS BUCODISPERSA- BLES EFG	5 mg	Orodispersible tablet	Oral use
Spain	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan	IRBESARTAN/HIDROCLOROTIA- ZIDA WELDING 150 mg/12,5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	150 mg/12,5 mg	Film-coated tablet	Oral use
Spain	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan	IRBESARTAN/HIDROCLOROTIA- ZIDA WELDING 300 mg/12,5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	300 mg/12,5 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan	IRBESARTAN/HIDROCLOROTIA- ZIDA WELDING 300 mg/25 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	300 mg/25 mg	Film-coated tablet	Oral use
Sweden	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Alendronic acid	Alendronat Accord Veckotablett	70 mg	Tablet	Oral use
Sweden	Alternova A/S Lodshusvej 11 DK-4230 Skælskør Denmark	Clindamycin hydro- chloride	Clindamycin Alternova	150 mg	Capsule, hard	Oral use
Sweden	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Fluconazole	Fluconazol Bluefish	50 mg	Capsule, hard	Oral use
Sweden	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Fluconazole	Fluconazol Bluefish	150 mg	Capsule, hard	Oral use
Sweden	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Fluconazole	Fluconazol Bluefish	200 mg	Capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Sweden	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Donepezil hydrochloride	Donezil	5 mg	Orodispersible tablet	Oral use
Sweden	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Donepezil hydrochloride	Donezil	10 mg	Orodispersible tablet	Oral use
Sweden	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Donepezil	Donepezil Mylan	5 mg	Orodispersible tablet	Oral use
Sweden	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Donepezil	Donepezil Mylan	10 mg	Orodispersible tablet	Oral use
Sweden	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Rizatriptan	Rizatriptan Mylan	10 mg	Orodispersible tablet	Oral use
Sweden	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Repaglinide	Repaglinid Mylan	0,5 mg	Tablet	Oral use
Sweden	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Repaglinide	Repaglinid Mylan	1 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Sweden	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Repaglinide	Repaglinid Mylan	2 mg	Tablet	Oral use
Sweden	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Esomeprazole	Esomeprazol Mylan	20 mg	Gastro-resistant capsule, hard	Oral use
Sweden	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Esomeprazole	Esomeprazol Mylan	40 mg	Gastro-resistant capsule, hard	Oral use
Sweden	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Eletriptan	Eletriptan Mylan	20 mg	Film-coated tablet	Oral use
Sweden	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Eletriptan	Eletriptan Mylan	40 mg	Film-coated tablet	Oral use
Sweden	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	Valsartan Orion	40 mg	Film-coated tablet	Oral use
Sweden	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	Valsartan Orion	80 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Sweden	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	Valsartan Orion	160 mg	Film-coated tablet	Oral use
Sweden	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	Valsartan Orion	320 mg	Film-coated tablet	Oral use
Sweden	Ranbaxy UK Ltd Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE United Kingdom	Alendronic acid	Alendronat Ranbaxy Veckotablett 70 mg tabletter	70 mg	Tablet	Oral use
Sweden	Stada Arzneimittel AG Stadastrasse 2-18 DE-61118 Bad Vilbel Germany	Entacapone	Entakapon STADA	200 mg	Film-coated tablet	Oral use
The Netherlands	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirol Accord 5 mg, filmom- hulde tabletten	5 mg	Film-coated tablet	Oral use
The Netherlands	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirol Accord 0,25 mg filmom- hulde tabletten	0,25 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirol Accord 0,5 mg filmom- hulde tabletten	0,5 mg	Film-coated tablet	Oral use
The Netherlands	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirol Accord 1 mg filmom- hulde tabletten	1 mg	Film-coated tablet	Oral use
The Netherlands	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirol Accord 2 mg filmom- hulde tabletten	2 mg	Film-coated tablet	Oral use
The Netherlands	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Alendronic acid	Alendroninezuur Accord 10 mg Tabletten	10 mg	Tablet	Oral use
The Netherlands	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Alendronic acid	Alendroninezuur Accord 70 mg Tabletten	70 mg	Tablet	Oral use
The Netherlands	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Metoclopramide hydrochloride	Metoclopramidemonohydrochlor- ide Accord 10 mg Tabletten	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Alembic Pharmaceuticals Europe Limited Palazzo Pietro Stiges, 103, Strait Street VLT 1436 Valletta Malta	Venlafaxine	Venlafaxine HCl Retard Alembic 37,5 mg, capsule met verlengde afgifte, hard	37,5 mg	Prolonged — release capsule, hard	Oral use
The Netherlands	Alembic Pharmaceuticals Europe Limited Palazzo Pietro Stiges, 103, Strait Street VLT 1436 Valletta Malta	Venlafaxine	Venlafaxine HCl Retard Alembic 75 mg, capsule met verlengde afgifte, hard	75 mg	Prolonged — release capsule, hard	Oral use
The Netherlands	Alembic Pharmaceuticals Europe Limited Palazzo Pietro Stiges, 103, Strait Street VLT 1436 Valletta Malta	Venlafaxine	Venlafaxine HCl Retard Alembic 150 mg, capsule met verlengde afgifte, hard	150 mg	Prolonged — release capsule, hard	Oral use
The Netherlands	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Ebastine	Ebastine BB 10 mg orodispergeerbare tabletten	10 mg	Orodispersible tablet	Oral use
The Netherlands	Centrafarm B.V. Nieuwe Donk 3 4879 AC Etten Leur The Netherlands	Entacapone	Entacapone CF 200 mg, filmomhulde tablet	200 mg	Film-coated tablet	Oral use
The Netherlands	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Ciprofloxacin	Ciprofloxacin Fair-Med 250 mg, filmomhulde tabletten	250 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Ciprofloxacin	Ciprofloxacin Fair-Med 500 mg, filmomhulde tabletten	500 mg	Film-coated tablet	Oral use
The Netherlands	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Ciprofloxacin	Ciprofloxacin Fair-Med 750 mg, filmomhulde tabletten	750 mg	Film-coated tablet	Oral use
The Netherlands	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochloro- thiazide	Valsartan/HCTZ Fair-Med 160 mg/ 12,5 mg, filmomhulde tabletten	160 mg/12,5 mg	Film-coated tablet	Oral use
The Netherlands	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochloro- thiazide	Valsartan/HCTZ Fair-Med 320 mg/ 12,5 mg, filmomhulde tabletten	320 mg/12,5 mg	Film-coated tablet	Oral use
The Netherlands	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochloro- thiazide	Valsartan/HCTZ Fair-Med 320 mg/ 25 mg, filmomhulde tabletten	320 mg/25 mg	Film-coated tablet	Oral use
The Netherlands	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Venlafaxine	Venlafaxine Fair-Med 37,5 mg cap- sules met verlengde afgifte, hard	37,5 mg	Prolonged — release capsule, hard	Oral use
The Netherlands	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Venlafaxine	Venlafaxine Fair-Med 75 mg cap- sules met verlengde afgifte, hard	75 mg	Prolonged — release capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Venlafaxine	Venlafaxine Fair-Med 150 mg capsules met verlengde afgifte, hard	150 mg	Prolonged — release capsule, hard	Oral use
The Netherlands	Mylan B.V. Dieselweg 25 3752 LB Bunschoten The Netherlands	Esomeprazole	Esomeprazol Mylan 20 mg, maag-sapresistente capsules, hard	20 mg	Gastro-resistant capsule, hard	Oral use
The Netherlands	Mylan B.V. Dieselweg 25 3752 LB Bunschoten The Netherlands	Esomeprazole	Esomeprazol Mylan 40 mg, maag-sapresistente capsules, hard	40 mg	Gastro-resistant capsule, hard	Oral use
The Netherlands	Mylan B.V. Dieselweg 25 3752 LB Bunschoten The Netherlands	Rizatriptan	Rizatriptan SmeltTab Mylan 5 mg, orodispergeerbare tabletten	5 mg	Orodispersible tablet	Oral use
The Netherlands	Mylan B.V. Dieselweg 25 3752 LB Bunschoten The Netherlands	Rizatriptan	Rizatriptan SmeltTab Mylan 10 mg, orodispergeerbare tabletten	10 mg	Orodispersible tablet	Oral use
The Netherlands	Ranbaxy UK Ltd Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE United Kingdom	Alendronic acid	Alendroninezuur 70 Ranbaxy, tabletten 70 mg	70 mg	Tablet	Oral use
The Netherlands	Sandoz B.V. Veluwezoom 22 1327 AH Almere The Netherlands	Clonazepam	Clonazepam Sandoz 0,5 mg, tabletten	0,5 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Sandoz B.V. Veluwezoom 22 1327 AH Almere The Netherlands	Clonazepam	Clonazepam Sandoz 2 mg, tabletten	2 mg	Tablet	Oral use
The Netherlands	Sandoz B.V. Veluwezoom 22 1327 AH Almere The Netherlands	Clobazam	Clobazam Sandoz 10 mg, tabletten	10 mg	Tablet	Oral use
The Netherlands	Teva Nederland B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Desloratadine	Desloratadine Smelttablet 2,5 mg Teva, orodispergeerbare tabletten	2,5 mg	Orodispersible tablet	Oral use
The Netherlands	Teva Nederland B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Desloratadine	Desloratadine Smelttablet 5 mg Teva, orodispergeerbare tabletten	5 mg	Orodispersible tablet	Oral use
The Netherlands	TioFarma b.v. Benjamin Franklinstraat 5-10 3261 LW Oud-Beyerland The Netherlands	Clonazepam	Clonazepam TioFarma 0,5 mg ta- bletten, tabletten	0,5 mg	Tablet	Oral use
The Netherlands	TioFarma b.v. Benjamin Franklinstraat 5-10 3261 LW Oud-Beyerland The Netherlands	Clonazepam	Clonazepam TioFarma 2 mg table- tten, tabletten	2 mg	Tablet	Oral use
The Netherlands	TioFarma b.v. Benjamin Franklinstraat 5-10 3261 LW Oud-Beyerland The Netherlands	Clobazam	Clobazam TioFarma 10 mg, table- tten	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	TioFarma b.v. Benjamin Franklinstraat 5-10 3261 LW Oud-Beyerland The Netherlands	Clobazam	Clobazam TioFarma 20 mg, tabletten	20 mg	Tablet	Oral use
The Netherlands	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	irbesartan	Irbesartan Torrent 75 mg filmomhulde tabletten	75 mg	Film-coated tablet	Oral use
The Netherlands	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	irbesartan	Irbesartan Torrent 150 mg filmomhulde tabletten	150 mg	Film-coated tablet	Oral use
The Netherlands	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	irbesartan	Irbesartan Torrent 300 mg filmomhulde tabletten	300 mg	Film-coated tablet	Oral use
The Netherlands	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydrochlorothiazide	Irbesartan Hydrochlorothiazide Torrent 150 mg/12,5 mg filmomhulde tabletten	150 mg/12,5 mg	Film-coated tablet	Oral use
The Netherlands	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydrochlorothiazide	Irbesartan Hydrochlorothiazide Torrent 300 mg/12,5 mg filmomhulde tabletten	300 mg/12,5 mg	Film-coated tablet	Oral use
The Netherlands	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydrochlorothiazide	Irbesartan Hydrochlorothiazide Torrent 300 mg/25 mg filmomhulde tabletten	300 mg/25 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Unichem Laboratories Ltd Studio 8B Ard Gaoithe Commercial Centre, Business Park Cashel Road Clonmel, Co Tipperary Ireland	irbesartan	Irbesartan Unichem 150 mg film-coated tablets	150 mg	Film-coated tablet	Oral use
The Netherlands	Unichem Laboratories Ltd Studio 8B Ard Gaoithe Commercial Centre, Business Park Cashel Road Clonmel, Co Tipperary Ireland	irbesartan	Irbesartan Unichem 300 mg film-coated tablets	300 mg	Film-coated tablet	Oral use
United Kingdom	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirole 0,25 mg film-coated tablets	0,25 mg	Film-coated tablet	Oral use
United Kingdom	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirole 0,5 mg film-coated tablets	0,5 mg	Film-coated tablet	Oral use
United Kingdom	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirole 1 mg film-coated tablets	1 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirole 2 mg film-coated tablets	2 mg	Film-coated tablet	Oral use
United Kingdom	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Alendronic acid	alendronic acid 10 mg Tablets	10 mg	Tablet	Oral use
United Kingdom	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Alendronic acid	alendronic acid 70 mg Once Daily Tablets	70 mg	Tablet	Oral use
United Kingdom	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Metoclopramide hydrochloride	metoclopramide hydrochloride 10 mg tablets	10 mg	Tablet	Oral use
United Kingdom	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirole 5 mg film-coated tablets	5 mg	Film-coated tablet	Oral use
United Kingdom	Aptil Pharma Limited 9th Floor, CP House 97-107 Uxbridge Road London W5 5TL United Kingdom	Fluconazole	Fluconazole 50 mg capsules	50 mg	Capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Aptil Pharma Limited 9th Floor, CP House 97-107 Uxbridge Road London W5 5TL United Kingdom	Fluconazole	Fluconazole 150 mg capsules	150 mg	Capsule, hard	Oral use
United Kingdom	Aptil Pharma Limited 9th Floor, CP House 97-107 Uxbridge Road London W5 5TL United Kingdom	Fluconazole	Fluconazole 200 mg capsules	200 mg	Capsule, hard	Oral use
United Kingdom	Auden McKenzie Limited McKenzie House Bury Street, Ruislip Middlesex HA4 7TL United Kingdom	Dexamethasone	Dexamethasone 2 mg Tablets	2 mg	Tablet	Oral use
United Kingdom	Auden McKenzie Limited McKenzie House Bury Street, Ruislip Middlesex HA4 7TL United Kingdom	Thiamine hydrochloride	Tyvera 50 mg Tablets	50 mg	Tablet	Oral use
United Kingdom	Auden McKenzie Limited McKenzie House Bury Street, Ruislip Middlesex HA4 7TL United Kingdom	Thiamine hydrochloride	Tyvera 100 mg Tablets	100 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Auden McKenzie Limited McKenzie House Bury Street, Ruislip Middlesex HA4 7TL United Kingdom	Clonazepam	Clonazepam 500 mcg Tablet	0,5 mg	Tablet	Oral use
United Kingdom	Auden McKenzie Limited McKenzie House Bury Street, Ruislip Middlesex HA4 7TL United Kingdom	Clonazepam	Clonazepam 2 mg Tablet	2 mg	Tablet	Oral use
United Kingdom	Auden McKenzie Limited McKenzie House Bury Street, Ruislip Middlesex HA4 7TL United Kingdom	Clobazam	CLOBAZAM AUDEN 10 mg TA-BLETS	10 mg	Tablet	Oral use
United Kingdom	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Phenoxymethyl penicillin	Phenoxymethylpenicillin 250 mg Film-coated Tablets	250 mg	Film-coated tablet	Oral use
United Kingdom	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram oxalate	Escitalopram 5 mg Film-coated tablets	5 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram oxalate	Escitalopram 10 mg Film-coated tablets	10 mg	Film-coated tablet	Oral use
United Kingdom	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram oxalate	Escitalopram 15 mg Film-coated tablets	15 mg	Film-coated tablet	Oral use
United Kingdom	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram oxalate	Escitalopram 20 mg Film-coated tablets	20 mg	Film-coated tablet	Oral use
United Kingdom	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Tramadol hydrochloride	Accon 100 mg Prolonged-release tablets	100 mg	Prolonged-release tablet	Oral use
United Kingdom	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Tramadol hydrochloride	Accon 150 mg Prolonged-release tablets	150 mg	Prolonged-release tablet	Oral use
United Kingdom	Brown & Burk UK, Ltd 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Tramadol hydrochloride	Accon 200 mg Prolonged-release tablets	200 mg	Prolonged-release tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Valsartan	Valsartan 40 mg Capsules	40 mg	Capsule	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Valsartan	Valsartan 80 mg Capsules	80 mg	Capsule	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Valsartan	Valsartan 160 mg Capsules	160 mg	Capsule	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Valsartan	Valsartan 320 mg Capsules	320 mg	Capsule	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Levetiracetam	Levetiracetam 250 mg film-coated tablets	250 mg	Film-coated tablet	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Levetiracetam	Levetiracetam 500 mg film-coated tablets	500 mg	Film-coated tablet	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Levetiracetam	Levetiracetam 750 mg film-coated tablets	750 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Levetiracetam	Levetiracetam 1 000 mg film-coated tablets	1 000 mg	Film-coated tablet	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Pioglitazone	Pioglitazone 15 mg Tablets	15 mg	Tablet	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Pioglitazone	Pioglitazone 30 mg Tablets	30 mg	Tablet	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Pioglitazone	Pioglitazone 45 mg Tablets	45 mg	Tablet	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Dipyridamole	Attia 200 mg Modified Release Capsules	200 mg	Modified-release capsule, hard	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Telmisartan	Telmisartan 20 mg Tablets	20 mg	Tablet	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Telmisartan	Telmisartan 40 mg Tablets	40 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Telmisartan	Telmisartan 80 mg Tablets	80 mg	Tablet	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Telmisartan/ hydrochlorothiazide	Telmisartan/Hydrochlorothiazide 40 mg/12,5 mg Tablets	40 mg/12,5 mg	Tablet	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Telmisartan/ hydrochlorothiazide	Telmisartan/Hydrochlorothiazide 80 mg/12,5 mg Tablets	80 mg/12,5 mg	Tablet	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Telmisartan/ hydrochlorothiazide	Telmisartan/Hydrochlorothiazide 80 mg/25 mg Tablets	80 mg/25 mg	Tablet	Oral use
United Kingdom	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	irbesartan	Irbesartan 75 mg Film-coated Tablets	75 mg	Film-coated tablet	Oral use
United Kingdom	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	irbesartan	Irbesartan 150 mg Film-coated Tablets	150 mg	Film-coated tablet	Oral use
United Kingdom	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	irbesartan	Irbesartan 300 mg Film-coated Tablets	300 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan/Hydrochlorothiazide 150 mg/12,5 mg film-coated tablets	150 mg/12,5 mg	Film-coated tablet	Oral use
United Kingdom	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan/Hydrochlorothiazide 300 mg/12,5 mg film-coated tablets	300 mg/12,5 mg	Film-coated tablet	Oral use
United Kingdom	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan/Hydrochlorothiazide 300 mg/25 mg film-coated tablets	300 mg/25 mg	Film-coated tablet	Oral use
United Kingdom	Fannin (UK) Ltd 42-46 Booth Drive Park Farm South Wellingborough Northamptonshire NN8 6GT United Kingdom	Fluconazole	Fluconazole 150 mg capsule	150 mg	Capsule, hard	Oral use
United Kingdom	Fannin (UK) Ltd 42-46 Booth Drive Park Farm South Wellingborough Northamptonshire NN8 6GT United Kingdom	Fexofenadine	Fexofenadine 120 mg film-coated tablets	120 mg	Film-coated tablet	Oral use
United Kingdom	Fannin (UK) Ltd 42-46 Booth Drive Park Farm South Wellingborough Northamptonshire NN8 6GT United Kingdom	Fexofenadine	Fexofenadine 180 mg film-coated tablets	180 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	FDC Pharma Unit 6, Fulcrum 1, Solent Way Whiteley, Fareham Hampshire PO15 7FE United Kingdom	Amlodipine	Amlodipine 5 mg Tablets	5 mg	Tablet	Oral use
United Kingdom	FDC Pharma Unit 6, Fulcrum 1, Solent Way Whiteley, Fareham Hampshire PO15 7FE United Kingdom	Amlodipine	Amlodipine 10 mg Tablets	10 mg	Tablet	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Repaglinide	Repaglinide Mylan 0,5 mg Tablets	0,5 mg	Tablet	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Repaglinide	Repaglinide Mylan 1 mg Tablets	1 mg	Tablet	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Repaglinide	Repaglinide Mylan 2 mg Tablets	2 mg	Tablet	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Donepezil hydrochloride	Donepezil Hydrochloride 5 mg Orodispersible Tablets	5 mg	Orodispersible tablet	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Donepezil hydrochloride	Donepezil Hydrochloride 10 mg Orodispersible Tablets	10 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Rizatriptan benzoate	Rizatriptan 10 mg Orodispersible Tablet	10 mg	Orodispersible tablet	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Esomeprazole magnesium	Esomeprazole 20 mg Gastro-resistant Capsules, hard	20 mg	Gastro-resistant capsule	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Esomeprazole magnesium	Esomeprazole 40 mg Gastro-resistant Capsules, hard	40 mg	Gastro-resistant capsule	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Levodopa/carbidopa/entacapone	Levodopa/Carbidopa/Entacapone film-coated tablets 150/37,5/200 mg	150 mg/ 37,5 mg/200 mg	Film-coated tablet	Oral use
United Kingdom	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 0PF United Kingdom	Pantoprazole	Pantoprazole 20 mg Gastro-Resistant tablets	20 mg	Gastro-resistant tablet	Oral use
United Kingdom	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 0PF United Kingdom	Pantoprazole	Pantoprazole 40 mg Gastro-Resistant tablets	40 mg	Gastro-resistant tablet	Oral use
United Kingdom	Morningside Healthcare Limited 115 Narborough Road Leicester, LE3 0PA United Kingdom	Phenoxymethyl penicillin	Phenoxymethylpenicillin 250 mg Film-coated Tablets	250 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Morningside Healthcare Limited 115 Narborough Road Leicester, LE3 0PA United Kingdom	Metformin hydrochloride	Bolamyn/Metabet SR 1 000 mg Prolonged Release Tablets	1 000 mg	Prolonged-release tablet	Oral use
United Kingdom	Niche Generics Limited 1 The Cam Centre Wilbury Way, Hitchin Hertfordshire SG4 0TW United Kingdom	irbesartan	Irbesartan Niche 150 mg film-coated tablets	150 mg	Film-coated tablet	Oral use
United Kingdom	Niche Generics Limited 1 The Cam Centre Wilbury Way, Hitchin Hertfordshire SG4 0TW United Kingdom	irbesartan	Irbesartan Niche 150 mg film-coated tablets	150 mg	Film-coated tablet	Oral use
United Kingdom	Ranbaxy UK Ltd Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE United Kingdom	Alendronic acid	Alendronic Acid 70 mg Tablets	70 mg	Tablet	Oral use
United Kingdom	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydrochlorothiazide	Irbesartan Hydrochlorothiazide 150 mg/12,5 mg Film-coated tablets	150 mg/12,5 mg	Film-coated tablet	Oral use
United Kingdom	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydrochlorothiazide	Irbesartan Hydrochlorothiazide 300 mg/12,5 mg Film-coated tablets	300 mg/12,5 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydrochlorothiazide	Irbesartan Hydrochlorothiazide 300 mg/25 mg Film-coated tablets	300 mg/25 mg	Film-coated tablet	Oral use
United Kingdom	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	irbesartan	Irbesartan 75 mg Film-coated tablets	75 mg	Film-coated tablet	Oral use
United Kingdom	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	irbesartan	Irbesartan 150 mg Film-coated tablets	150 mg	Film-coated tablet	Oral use
United Kingdom	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	irbesartan	Irbesartan 300 mg Film-coated tablets	300 mg	Film-coated tablet	Oral use
United Kingdom	Waymade PLC Sovereign House Miles Grate Road, Basildon Essex SS14 3FR United Kingdom	Venlafaxine hydrochloride	Venlasov XL 75 mg Modified Release Capsules	75 mg	Prolonged-release capsule, hard	Oral use
United Kingdom	Waymade PLC Sovereign House Miles Grate Road, Basildon Essex SS14 3FR United Kingdom	Venlafaxine hydrochloride	Venlasov XL 150 mg Modified Release Capsules	150 mg	Prolonged-release capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Wockhardt UK Limited Ash Road North Wrexham Industrial Estate Wrexham LL13 9UF United Kingdom	Clopidogrel	Clopidogrel 75 mg Film-coated Tablets	75 mg	Film-coated tablet	Oral use
United Kingdom	YJBPort Limited 74 Briarwood Drive Northwood Hills Middlesex HA6 1PL United Kingdom	Hydrocortisone	Hydrocortisone 10 mg Tablets	10 mg	Tablet	Oral use
United Kingdom	YJBPort Limited 74 Briarwood Drive Northwood Hills Middlesex HA6 1PL United Kingdom	Hydrocortisone	Hydrocortisone 20 mg Tablets	20 mg	Tablet	Oral use

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