

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 - released capsule, hard	Oral use
Austria	Basics GmbH Hemmelrather Weg 201 51377 Leverkusen Germany	Venlafaxine	Venlafaxin Ranbaxy 75 mg Retardkapseln	75 mg	Prolonged - released capsule, hard	Oral use
Austria	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxin Bluefish 75mg Hartkapseln retardiert	75 mg	Prolonged - released capsule, hard	Oral use
Austria	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxin Bluefish 150mg Hartkapseln retardiert	150mg	Prolonged - released capsule, hard	Oral use
Austria	G.L. Pharma GmbH Schlossplatz 1 8502 Lannach Austria	Nebivolol	Nebilan 5mg 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. Šlandrova 4 1231 Ljubljana - Črnuče Slovenia	Levetiracetam	Lyvam	250 mg	Film - coated tablet	Oral use
Bulgaria	Alkaloid - INT d.o.o. Šlandrova 4 1231 Ljubljana - Črnuče Slovenia	Levetiracetam	Lyvam	500 mg	Film - coated tablet	Oral use
Bulgaria	Alkaloid - INT d.o.o. Šlandrova 4 1231 Ljubljana - Črnuče Slovenia	Levetiracetam	Lyvam	750 mg	Film - coated tablet	Oral use
Bulgaria	Alkaloid - INT d.o.o. Šlandrova 4 1231 Ljubljana - Črnuče Slovenia	Levetiracetam	Lyvam	1000 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

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	120 mg	Film - coated tablet	Oral use
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

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 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
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 1000 mg filmom obložene tablete	1000 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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
Czech Republic	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxine Bluefish 75 mg	75 mg	Prolonged - released capsule, hard	Oral use
Czech Republic	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxine Bluefish 150 mg	150 mg	Prolonged - released capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
Czech Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Levetiracetam	Letiramyl 1000 mg potahované tablety	1000 mg	Film - coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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. Wałbrzyska 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 Chanelle Generics Limited Athenry Road, Loughrea, Co Galway Ireland	Fexofenadine	Alterfast	120 mg	Film - coated tablet	Oral use
Denmark	Cipla Chanelle Generics Limited Athenry Road, Loughrea, Co Galway Ireland	Fexofenadine	Alterfast	180 mg	Film - coated tablet	Oral use
Denmark	Cipla Chanelle Generics Limited Athenry Road, Loughrea, Co Galway Ireland	Fexofenadine	Clarifast	120 mg	Film - coated tablet	Oral use
Denmark	Cipla Chanelle Generics Limited Athenry Road, Loughrea, Co Galway Ireland	Fexofenadine	Clarifast	180 mg	Film - coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Denmark	Cipla Chanelle Generics Limited Athenry Road, Loughrea, Co Galway Ireland	Fexofenadine	Histafast	120 mg	Film - coated tablet	Oral use
Denmark	Cipla Chanelle 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

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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
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 5MG	5 mg	Tablet	Oral use
Estonia	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	VENLAFAXINE ORION	37,5 mg	Prolonged - released capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Estonia	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	VENLAFAXINE ORION	75 mg	Prolonged - released capsule, hard	Oral use
Estonia	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	VENLAFAXINE ORION	150 mg	Prolonged - released capsule, hard	Oral use
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 Noramed Meistru 8a Vilnius LT-02189 Lithuania	Bosentan	BOSENTAN NORAMEDA 62,5 MG	62,5 mg	Film - coated tablet	Oral use
Estonia	UAB Noramed Meistru 8a Vilnius LT-02189 Lithuania	Bosentan	BOSENTAN NORAMEDA 125 MG	125 mg	Film - coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Estonia	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	VENLAGAMMA 75 MG	75 mg	Prolonged - released capsule, hard	Oral use
Estonia	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	VENLAGAMMA 150 MG	150 mg	Prolonged - released capsule, hard	Oral use
Finland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxine Bluefish	75 mg	Prolonged - released capsule, hard	Oral use
Finland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxine Bluefish	150 mg	Prolonged - released capsule, hard	Oral use
Finland	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Fexofenadine	Nefoxef	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 - released capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Finland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine hydrochloride	VENLAFAXIN ORION	75 mg	Prolonged - released capsule, hard	Oral use
Finland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine hydrochloride	VENLAFAXIN ORION	150 mg	Prolonged - released 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 BIOGARAN 120 mg, comprimé pelliculé	120 mg	Film - coated tablet	Oral use
France	BIOGARAN 15, boulevard Charles de Gaulle 92707 Colombes Cedex	Fexofenadine	FEXOFENADINE BIOGARAN 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

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	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 250mg, comprimé pelliculé	250 mg	Tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Levetiracetam	LEVETIRACETAM MYLAN PHARMA 500mg, comprimé pelliculé	500 mg	Tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Levetiracetam	LEVETIRACETAM MYLAN PHARMA 1000mg, comprimé pelliculé	1000 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 quadrisécable	5 mg	Tablet	Oral use
France	Ranbaxy Pharmacie Generiques 11-15 Quai Dion Bouton 92800 Puteaux France	Venlafaxine	Venlafaxine Ranbaxy LP 37,5mg, gélule à libération prolongée	37,5 mg	Prolonged - release capsule	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 75mg, 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 150mg, 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 quadrisécable	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 - released capsule, hard	Oral use
Germany	AAA-Pharma GmbH Liebknechtstrasse 33 70565 Stuttgart Germany	Venlafaxine	Venlafaxin AAA 150 mg Hartkapseln, retardiert	150 mg	Prolonged - released 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 - released capsule, hard	Oral use
Germany	Alfred E. Tiefenbacher GmbH Van-der-Smissen-Strasse 1 D-22767 Hamburg Germany	Levocetirizine	Levocetira 5 mg Filmtabletten	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 - released capsule, hard	Oral use
Germany	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxin Bluefish 150 mg Hartkapsel, retardiert	15 mg	Prolonged - released capsule, hard	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 120 mg Filmtabletten	120 mg	Film - coated tablet	Oral use
Germany	Dermapharm Aktiengesellschaft Lil-Dagover-Ring 7 82031 Grünwald Germany	Fexofenadine	Fexofenaderm 180mg 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, retardiert	37,5 mg	Prolonged - released 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, retardiert	75 mg	Prolonged - released 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, retardiert	150 mg	Prolonged - released capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	G.L. Pharma GmbH Schlossplatz 1 8502 Lannach Austria	Nebivolol	NEBITEN 5MG	5 mg	Tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 90449 Nürnberg Germany	Venlafaxine	Venlafaxin Heumann 37,5 mg Hartkapseln, retardiert	37,5 mg	Prolonged - released capsule, hard	Oral use
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

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 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 1000 mg Filmtabletten	1000 mg	Film - coated tablet	Oral use
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm Germany	Nebivolol	NEBIVOLOL- RATIOPHARM 5mg	5 mg	Tablet	Oral use
Germany	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Nebivolol	Nebivolol Torrent 5 mg Tabletten	5 mg	Tablet	Oral use
Germany	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma retard 37.5 mg Hartkapseln, retardiert	37,5 mg	Prolonged - released capsule, hard	Oral use
Germany	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma retard 75 mg Hartkapseln, retardiert	75 mg	Prolonged - released capsule, hard	Oral use
Germany	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma retard 150 mg hartkapseln, retardiert	150 mg	Prolonged - released capsule, hard	Oral use
Greece	Pharmazac SA 31 Naoussis street Athens 1447 Greece	Venlafaxine	Zacalen pr cap 75mg/cap	75 mg	Prolonged - released 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 150mg/cap	150 mg	Prolonged - released 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 - released 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 - released 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 - released 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 - released capsule, hard	Oral use
Iceland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxine Bluefish	150 mg	Prolonged - released capsule, hard	Oral use
Iceland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxine Bluefish	37,5 mg	Prolonged - released capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Iceland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxine Bluefish	75 mg	Prolonged - released capsule, hard	Oral use
Iceland	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Fexofenadine	Nefoxef	120 mg	Film - coated tablet	Oral use
Iceland	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Fexofenadine	Nefoxef	180 mg	Film - coated tablet	Oral use
Ireland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 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-11123 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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
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	Levcetin 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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
Italy	FB Health S.p.A. Via dei Sabini, 28 63100 - Ascoli Piceno Italy	Venlafaxine	IXILANIA	150 mg	Prolonged - released capsule, hard	Oral use
Italy	Germed 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 GENERICS	250 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	Levetiracetam	LEVETIRACETAM MYLAN GENERICS	750 mg	Film - coated tablet	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Levetiracetam	LEVETIRACETAM MYLAN GENERICS	500 mg	Film - coated tablet	Oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Levetiracetam	LEVETIRACETAM MYLAN GENERICS	1000 mg	Film - coated tablet	Oral use
Italy	MylanS.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Fexofenadine	FEXOFENADINA MYLAN GENERICS	120 mg	Film - coated tablet	Oral use
Italy	MylanS.P.A. Via Vittor Pisani, 20 20124 Milan Italy	Fexofenadine	FEXOFENADINA MYLAN GENERICS	180 mg	Film - coated tablet	Oral use
Italy	Pensa Pharma S.P.A. Via Rossellini Ippolito, 12 20124 Milan Italy	Venlafaxine	VENLAFAXINA PENZA	75 mg	Prolonged - released capsule, hard	Oral use
Italy	Pensa Pharma S.P.A. Via Rossellini Ippolito, 12 20124 Milan Italy	Venlafaxine	VENLAFAXINA PENZA	150 mg	Prolonged - released capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Italy	Progefarm S.r.l. Largo Donegani 4/A 28100 - Novara Italy	Venlafaxine	VENLAFAXINA PROGE FARM	75 mg	Prolonged - released capsule, hard	Oral use
Italy	Progefarm S.r.l. Largo Donegani 4/A 28100 - Novara Italy	Venlafaxine	VENLAFAXINA PROGE FARM	150 mg	Prolonged - released 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 - released 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 - released capsule, hard	Oral use
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
Latvia	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	Bosentan	Bosentan Sandoz	125 mg	Film - coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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 - released capsule, hard	Oral use
Lithuania	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	Venlafaxine Orion	75 mg	Prolonged - released capsule, hard	Oral use
Lithuania	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	Venlafaxine Orion	150 mg	Prolonged - released 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

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	75 mg	Prolonged - released capsule, hard	Oral use
Norway	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlafaxin Bluefish	150 mg	Prolonged - released 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. Wałbrzyska 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 - released capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxine Bluefish XL	150 mg	Prolonged - released capsule, hard	Oral use
Poland	Celon Pharma S.A. Ogrodowa 2A, Kiełpin 05-092 Łomianki, Poland	Bosentan	Bosentan Celon	125 mg	Film - coated tablet	Oral use
Poland	Farmaceutyczna Spółdzielnia Pracy Galena Krucza 62 50-984 Wrocław Poland	Fexofenadine hydrochloride	Fexofast 120 mg	120 mg	Film - coated tablet	Oral use
Poland	Farmaceutyczna Spółdzielnia Pracy Galena 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

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	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	1000 mg	Film - coated tablet	Oral use
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 - released capsule, hard	Oral use
Poland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	Oriven	75 mg	Prolonged - released capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Venlafaxine	Oriven	150 mg	Prolonged - released capsule, hard	Oral use
Poland	Ranbaxy (Poland) Sp. z o.o. Kubickiego 11 02-954 Warszawa Poland	Lansoprazole	LANBAX	15 mg	Gastro - resistant tablet	Oral use
Poland	Ranbaxy (Poland) Sp. z o.o. Kubickiego 11 02-954 Warszawa Poland	Lansoprazole	LANBAX	30 mg	Gastro - resistant tablet	Oral use
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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 - released capsule, hard	Oral use
Poland	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma	37,5 mg	Prolonged - released capsule, hard	Oral use
Poland	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma	150 mg	Prolonged - released capsule, hard	Oral use
Poland	Zakłady Farmaceutyczne POLPHARMA S.A. Pelplińska 19 83-200 Starogard Gdański Poland	Fexofenadine hydrochloride	Telfexo 120 mg	120 mg	Film - coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Zakłady Farmaceutyczne POLPHARMA S.A. Pelplińska 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 - released capsule, hard	Oral use
Portugal	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxina Bluefish XR	150 mg	Prolonged - released 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 - released 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 - released 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 - released 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 - released 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 - released 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 - released 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

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	Nebivolol	Nebivolol Inventis	5 mg	tablet	Oral use
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	Germed Farmacêutica, Lda. Rua Alto do Montijo, 13 - 1º Dto - Edifício Monsanto Portela de Carnaxide 2790-012 Portela de Carnaxide Portugal"	Nebivolol	Nebivolol Germed	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

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, 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
Portugal	Labesfal, Genéricos, S.A. Av. Dr. Afonso Costa, nº 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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
Romania	Ranbaxy UK Ltd. Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE Untied 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 Untied Kingdom	Lansoprazole	LEVANT	30 mg	Gastro - resistant tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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 primate	5 mg	Tablet	Oral use
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

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 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
Slovak Republic	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma 37,50 mg	37,5 mg	Prolonged - released capsule, hard	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 75 mg	75 mg	Prolonged - released capsule, hard	Oral use
Slovak Republic	Wörwag Pharma GmbH & Co. KG Calwer Str. 7 71034 Böblingen Germany	Venlafaxine	Venlagamma 150 mg	150 mg	Prolonged - released capsule, hard	Oral use
Slovenia	Alkaloid - INT d.o.o. Šlandrova 4 1231 Ljubljana - Črnuče Slovenia	Levetiracetam	Lyvam 250 mg filmsko obložene 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 obložene 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 obložene tablete	750 mg	Film - coated tablet	Oral use
Slovenia	Alkaloid - INT d.o.o. Šlandrova 4 1231 Ljubljana - Črnuče Slovenia	Levetiracetam	Lyvam 1000 mg filmsko obložene tablete	1000 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 Urlabs 150 mg capsulas duras de liberacion prolongada efg	150 mg	Prolonged - released capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	Aristo Pharma Iberia, S.L, c/ Solana, 26, Torrejon de Ardoz, Madrid, 28850 Spain	Venlafaxine	Venlafaxina Retard Urlabs 75 mg capsulas duras de liberacion prolongada efg	75 mg	Prolonged - released capsule, hard	Oral use
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 OPF 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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
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 pelicula 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 pelicula efg	180 mg	Film - coated tablet	Oral use
Spain	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Levetiracetam	Levetiracetam Lupin 1000 mg comprimidos recubiertos con pelicula efg	1000 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	Levetiracetam	Levetiracetam Lupin 250 mg comprimidos recubiertos con pelicula 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 pelicula efg	500 mg	Film - coated tablet	Oral use
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

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	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
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 Untied Kingdom	Venlafaxine	Venlafaxin Ranbaxy 150 mg depotkapsel, hård	150 mg	Prolonged - released capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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 - released capsule, hard	Oral use
The Netherlands	Alfred E. Tiefenbacher GmbH Van-der-Smissen-Strasse 1 D-22767 Hamburg Germany	Levocetirizine	Levocetira 5 mg filmomhulde tablet	5 mg	Film - coated tablet	Oral use
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 verlengde afgifte, hard	37,5 mg	Prolonged - released capsule, hard	Oral use
The Netherlands	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxine Bluefish 37,5 mg, capsules met verlengde afgifte, 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
The Netherlands	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine	Venlafaxine Bluefish 37,5 mg, capsules met verlengde afgifte, hard	150 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 37,5 mg, capsules met verlengde afgifte, hard	37,5 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 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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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 Untied Kingdom	Lansoprazole	Lansoprazol Ranbaxy 15 mg, maagsapresistente capsules	15 mg	Gastro - resistant tablet	Oral use
The Netherlands	Ranbaxy UK Ltd. Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE Untied 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 Untied 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 Untied Kingdom	Venlafaxine	Venlafaxine Ranbaxy 150 mg, capsules met verlengde afgifte	150 mg	Prolonged - released capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	ratiopharm Nederland B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Fexofenadine	Fexofenadine HCl ratiopharm 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 37.5mg 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 75mg Prolonged Release Capsules Hard	75 mg	Prolonged - released capsule, hard	Oral use
United Kingdom	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Venlafaxine hydrochloride	Venlablue XL 150mg Prolonged Release Capsules Hard	150 mg	Prolonged - released capsule, hard	Oral use
United Kingdom	Chanelle Medical Dublin road Loughrea, Co. Galway Ireland	Fexofenadine	Fexofenadine 120mg film-coated tablets	120 mg	Film - coated tablet	Oral use
United Kingdom	Chanelle Medical Dublin road Loughrea, Co. Galway Ireland	Fexofenadine	Fexofenadine 180mg 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	Forum Products Limited Crown House 2-8 Gloucester Road Redhill Surrey RH1 1FH United Kingdom	Venlafaxine hydrochloride	Foraven XL 75mg 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 150mg 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 120mg Film-coated tablets	120 mg	Film - coated tablet	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Fexofenadine	Fexofenadine hydrochloride 180mg Film-coated tablets	180 mg	Film - coated tablet	Oral use
United Kingdom	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 OPF United Kingdom	Levetiracetam	Levetiracetam Lupin 250mg Film-coated tablets	250 mg	Film - coated tablet	Oral use
United Kingdom	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 OPF United Kingdom	Levetiracetam	Levetiracetam Lupin 500mg Film-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
United Kingdom	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 OPF United Kingdom	Levetiracetam	Levetiracetam Lupin 750mg Film-coated tablets	750 mg	Film - coated tablet	Oral use
United Kingdom	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 OPF United Kingdom	Levetiracetam	Levetiracetam Lupin 1000mg Film-coated tablets	1000 mg	Film - coated tablet	Oral use
United Kingdom	Morningside Healthcare Limited 115 Narborough Road Leicester, LE3 OPA United Kingdom	Venlafaxine hydrochloride	Vensir XL 75mg Prolonged Release Hard Capsules	75 mg	Prolonged - released capsule, hard	Oral use
United Kingdom	Morningside Healthcare Limited 115 Narborough Road Leicester, LE3 OPA United Kingdom	Venlafaxine hydrochloride	Vensir XL 150mg Prolonged Release Hard Capsules	150 mg	Prolonged - released capsule, hard	Oral use
United Kingdom	Teva UK Limited Brampton Road Hampden Park Sussex BN22 9AG United Kingdom	Fexofenadine	Fexofenadine 120mg 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	Teva UK Limited Brampton Road Hampden Park Sussex BN22 9AG United Kingdom	Fexofenadine	Fexofenadine 180mg 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
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 4mg Tabletten	4 mg	Tablet	Oral use
Austria	Arcana Arzneimittel GmbH Huetteldorfer Straße 299 1140 Wien Austria	Candesartan cilexetil	Candesartan Arcana 8mg Tabletten	8mg	Tablet	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	Candesartan cilexetil	Candesartan Arcana 16mg Tabletten	16 mg	Tablet	Oral use
Austria	Arcana Arzneimittel GmbH Huetteldorfer Straße 299 1140 Wien Austria	Candesartan cilexetil	Candesartan Arcana 32mg 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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Belgium	Mylan bvba/sprl Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Donepezil	Donepezil Odis Mylan	5 mg	Orodispersible tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Donepezil	Donepezil Odis Mylan	10 mg	Orodispersible tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan 0,5 mg Pharma	0,5 mg	Tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan 1 mg Pharma	1 mg	Tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan 2mg Pharma	2 mg	Tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Candesartan	Candesartan Mylan	8 mg	Tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Candesartan	Candesartan Mylan	16 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Belgium	Mylan bvba/sprl Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Candesartan	Candesartan Mylan	32 mg	Tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Esomeprazole	Esomeprazole Mylan	20 mg	Gastro - resistant capsule, hard	Oral use
Belgium	Mylan bvba/sprl Terhulpesteenweg 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
Belgium	Teva Pharma Belgium NV Laarstraat 16 2610 Wilrijk Belgium	Desloratadine	Desloratadine Teva	5 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Bulgaria	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Trimetazidine	Trimetazigen MR	35 mg	Prolonged - release tablet	Oral use
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
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/paraceta mol	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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
Cyprus	Delorbis Pharmaceuticals Ltd 17 Athinon Street Ergates Industrial Area 2643 Ergates P.O. Box 28629 2081 Lefkosia Cyprus	Entacapone	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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
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

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	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
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

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 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
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.ar.l. Rue Heienhaff 5 L-1736 Senningerberg Luxembourg	Desloratadine	Desloratadin Alvogen 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	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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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 dispergovatelne 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 dispergovatelne 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. Reykjavikurvegi 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/hydrochl orothiazide	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/hydrochl orothiazide	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/hydrochl orothiazide	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 70mg	70 mg	Tablet	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	Trimetazidine	ZIDMETIN	35 mg	Modified - release tablet	Oral use
Finland	Actavis Group PTC ehf. Reykjavikurvegi 76-78 220 Hafnarfjörður Iceland	Metformin	Metformin Actavis	500 mg	Prolonged - release tablet	Oral use
Finland	Actavis Group PTC ehf. Reykjavikurvegi 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

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	0,5 mg	Tablet	Oral use
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Finland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	VALSARTAN ORION	320 mg	Film - coated tablet	Oral use
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 5mg, comprimé pelliculé	5 mg	Film - coated tablet	Oral use
France	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	ESCITALOPRAM ABBOTT 10mg, comprimé pelliculé	10 mg	Film - coated tablet	Oral use
France	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	ESCITALOPRAM ABBOTT 15mg, comprimé pelliculé	15 mg	Film - coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	ESCITALOPRAM ABBOTT 20mg, 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 0,25mg, comprimé pelliculé	0,25 mg	Film - coated tablet	Oral use
France	ACCORD HEALTHCARE France SAS 45 Rue de Fbg de Roubaix 59000 Lille France	Ropinirole	Ropinirole Accord 0,5mg, 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 1mg, 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 2mg, comprimé pelliculé	2 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 5mg, 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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Brown & Burk UK, Ltd. 5, Marrayat 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	DES LorATADINE 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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Laboratoires GERDA 24 rue Erlanger 75016 PARIS France	Desloratadine	DESLORATADINE 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/paraceta mol	TRAMADOL PARACETAMOL NIALEX 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	DESLORATADINE 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 5mg, orodispersible tablet	5 mg	Orodispersible tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Rizatriptan	RIZATRIPTAN MYLAN 10 mg, orodispersible tablet	10 mg	Orodispersible tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Ebastine	EBASTINE MYLAN 10mg, film-coated tablet	10 mg	Film - coated 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 10mg, 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 secable	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 20mg, DR capsule	20 mg	Gastro - resistant capsule, hard	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Esomeprazole	ESOMEPRAZOLE MYLAN PHARMA 40mg, DR capsule	40 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	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 comprimé 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 comprimé 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	DESLORATADINE 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 pelliculé	10 mg	Film - coated tablet	Oral use
France	Venipharm SAS 4 Bureaux de la Colline 92213 Saint-Cloud France	Ebastine	EBARREN 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	EBONDE 10 mg comprimé pelliculé	10 mg	Film - coated tablet	Oral use
France	Venipharm SAS 4 Bureaux de la Colline 92213 Saint-Cloud France	Ebastine	EBONTAN 10 mg comprimé orodispersible	10 mg	Orodispersible tablet	Oral use
France	Venipharm SAS 4 Bureaux de la Colline 92213 Saint-Cloud France	Ebastine	EBACHOI 10 mg comprimé orodispersible	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/paraceta mol	TRAMADOL PARACETAMOL ZYDUS FRANCE 37,5 mg/325 mg comprimé pelliculé	37,5 mg/325 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	Ibuprofen	IBUPROFENE ZF 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	Desloratadine	DESLORATADINE 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

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	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 70MG	70 mg	Tablet	Oral use
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 1000 mg, Filmtabletten	1000 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	Irbesartan Tablets 75mg	75 mg	Film - coated tablet	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan	Irbesartan Tablets 150mg	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
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydroch lorothiazide	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/hydroch lorothiazide	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/hydroch lorothiazide	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/hydrochl orothiazide	Valsartan/HCTZ Fair-Med Healthcare 160 mg/12.5 mg Filmtabletten	160 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
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochl orothiazide	Valsartan/HCTZ Fair-Med Healthcare 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/hydrochl orothiazide	Valsartan/HCTZ Fair-Med Healthcare 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
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Venlafaxine	Venlafaxin Fair-Med 75 mg Hartkapseln, 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 Hartkapseln, 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

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	Ciprofloxacin	Ciprofloxacin Fair-Med Healthcare 250 mg Filmtabletten	250 mg	Film - coated tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 90449 Nürnberg Germany	Irbesartan	Irbesartan Heumann 75 mg Filmtabletten	75 mg	Film - coated tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 90449 Nürnberg Germany	Irbesartan	Irbesartan Heumann 150 mg Filmtabletten	150 mg	Film - coated tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 90449 Nürnberg Germany	Irbesartan	Irbesartan Heumann 300 mg Filmtabletten	300 mg	Film - coated tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydroch lorothiazide	Irbesartan/Hydrochlorothia zid Heumann 150 mg/12.5 mg Filmtabletten	150 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
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydroch lorothiazide	Irbesartan/Hydrochlorothia zid Heumann 300 mg/12.5 mg Filmtabletten	300 mg/12,5 mg	Film - coated tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydroch lorothiazide	Irbesartan/Hydrochlorothia zid Heumann 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 200mg Filmtabletten	200 mg	Film - coated tablet	Oral use
Germany	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 OPF United Kingdom	Trimetazidine hydrochloride	Lupamadazine 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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
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

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	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 Filmtabletten	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 Filmtabletten	300 mg	Film - coated tablet	Oral use
Germany	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan/hydroch lorothiazide	Irbesartan + Hidroclorotiazida Welding	300 mg/12,5 mg	Film - coated tablet	Oral use
Germany	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan/hydroch lorothiazide	Irbesartan + Hidroclorotiazida Welding	150 mg/12,5 mg	Film - coated tablet	Oral use
Germany	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan/hydroch lorothiazide	Irbesartan + Hidroclorotiazida Welding	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
Germany	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan	Irbesartan Welding	75 mg	Film - coated tablet	Oral use
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Greece	Abbott Laboratories Hellas ABEE Agiou Dimitriou 63 Alimos 17456 Greece	Escitalopram oxalate	Savandra	20 mg	Film - coated tablet	Oral use
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Greece	Generics Pharma Hellas Ltd 577a Vouliagmenis Avenue Argyroupoli 164-51 Athens Greece	Esomeprazole magnesium	Esomeprazole/ Generics	40 mg	Prolonged - release capsule	Oral use
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. Reykjavikurvegi 76-78 220 Hafnarfjörður Iceland	Metformin hydrochloride	Gluforlyn XR 500 mg retard tableta	500 mg	Prolonged - release tablet	Oral use
Hungary	Alvogen IPCo S.ar.l. Rue Heienhaff 5 L-1736 Senningerberg Luxembourg	Desloratadine	Alvotadin 5 mg filmtabletta	5 mg	Film - coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Hungary	Alvogen IPCo S.ar.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.ar.l. Rue Heienhaff 5 L-1736 Senningerberg Luxembourg	Desloratadine	Alvotadin 5 mg szájban diszpergálódó tabletta	5 mg	Orodispersible tablet	Oral use
Hungary	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Esomeprazole magnesium	Esomeprazol Mylan 20 mg gyomornedv-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 gyomornedv-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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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 diszpergálódó tabletta	2,5 mg	Orodispersible tablet	Oral use
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 hydrochloride	Ropinirole 0.25 mg Film-coated Tablets	0,25 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 0.5 mg Film- coated Tablets	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 hydrochloride	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 hydrochloride	Ropinirole 2 mg Film- coated Tablets	2 mg	Film - coated tablet	Oral use
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Ireland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochl orothiazide	Valsartan/Hydrochlorothiaz ide 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/hydrochl orothiazide	Valsartan/Hydrochlorothiaz ide 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/hydrochl orothiazide	Valsartan/Hydrochlorothiaz ide 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
Ireland	Fannin (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

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	Donepezil	Aripil Orotab 5mg Orodispersible Tablet	5 mg	Orodispersible tablet	Oral use
Ireland	McDermott Laboratories Ltd t/a Gerard Laboratories 35/36 Baldoyle Industrial Estate Grange Road Dublin 13 Ireland	Donepezil	Aripil Orotab 10mg Orodispersible Tablet	10 mg	Orodispersible tablet	Oral use
Ireland	McDermott Laboratories Ltd t/a Gerard Laboratories 35/36 Baldoyle 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 Baldoyle 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 4mg 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

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	Phenoxymethyl penicillin	Phenoxymethylpenicillin 250mg 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 5mg tablets	5 mg	Tablet	Oral use
Ireland	Niche Generics Limited 1 The Cam Centre Wilbury Way, Hitchin Hertfordshire SG4 0TW United Kingdom	Amlodipine besilate	Amlodipine Niche 10mg 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 150mg 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 300mg 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
Ireland	Wockhardt UK Limited Ash Road North Wrexham Industrial Estate Wrexham LL13 9UF United Kingdom	Clopidogrel hydrochloride	Clopidogrel 75mg 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
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	DESLORATADINA DOC GENERICI	5 mg	Film - coated tablet	Oral use
Italy	Doc Generici SRL Via Turati, 40 20121 Milano Italy	Desloratadine	DESLORATADINA DOC GENERICI	2,5 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Italy	Doc Generici SRL Via Turati, 40 20121 Milano Italy	Desloratadine	DES LorATADINA 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
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

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	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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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 ITALIA	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
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

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	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/hydroch lorothiazide	Irbesartanas/Hidrochlorotia zidas Torrent	150 mg/12,5 mg	Film - coated tablet	Oral use
Lithuania	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydroch lorothiazide	Irbesartanas/Hidrochlorotia zidas Torrent	300 mg/12,5 mg	Film - coated tablet	Oral use
Lithuania	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydroch lorothiazide	Irbesartanas/Hidrochlorotia zidas Torrent	300 mg/25 mg	Film - coated tablet	Oral use
Luxembourg	Mylan bvba/sprl Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan Pharma 0,5 mg tabletten	0,5 mg	Tablet	Oral use
Luxembourg	Mylan bvba/sprl Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan Pharma 1 mg tabletten	1 mg	Tablet	Oral use
Luxembourg	Mylan bvba/sprl Terhulpesteenweg 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 Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Esomeprazole	Esomeprazole Mylan	20 mg	Gastro - resistant capsule, hard	Oral use
Luxembourg	Mylan bvba/sprl Terhulpesteenweg 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/hydrochl orothiazide	Valsartan/hydrochlorthiazid "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/hydrochl orothiazide	Valsartan/hydrochlorthiazid "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/hydrochl orothiazide	Valsartan/hydrochlorthiazid "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 75mg Film-coated Tablets	75 mg	Film - coated tablet	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	irbesartan	Irbesartan Fairmed 150mg Film-coated Tablets	150 mg	Film - coated tablet	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	irbesartan	Irbesartan Fairmed 300mg Film-coated Tablets	300 mg	Film - coated tablet	Oral use
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydroch lorothiazide	Irbesartan/Hydrochlorothia zide Fairmed 150mg/12.5mg 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/hydroch lorothiazide	Irbesartan/Hydrochlorothia zide Fairmed 300mg/12.5mg 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/hydroch lorothiazide	Irbesartan/Hydrochlorothia zide Fairmed 300mg/25mg 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 75mg 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 75mg 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, orodispersible 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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Actavis Group PTC ehf. Reykjavikurvegi 76-78 220 Hafnarfjörður Iceland	Metformin	Metformin SR Actavis	750 mg	Film - coated tablet	Oral use
Poland	Adamed Sp. z o.o. Pieńków 149 05-152 Czosnów k. Warszawy Poland	Desloratadine	Desada	5 mg	Orodispersible tablet	Oral use
Poland	Adamed Sp. z o.o. Pieńków 149 05-152 Czosnów k. Warszawy Poland	Desloratadine	Hitaxa Fast	2,5 mg	Orodispersible tablet	Oral use
Poland	Adamed Sp. z o.o. Pieńków 149 05-152 Czosnów k. Warszawy Poland	Desloratadine	Hitaxa	2,5 mg	Orodispersible tablet	Oral use
Poland	Adamed Sp. z o.o. Pieńków 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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
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/hydrochl orothiazide	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/hydrochl orothiazide	Valsartan HCT 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
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
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/hydroch lorothiazide	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/hydroch lorothiazide	Irbesartan HCT Fair-Med	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
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydroch lorothiazide	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/hydrochl orothiazide	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
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, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Candesartan cilexetil	Kangen	8 mg	Tablet	Oral use
Poland	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Candesartan cilexetil	Kangen	16 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
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

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	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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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/paraceta mol	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

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	300 mg	Film - coated tablet	Oral use
Portugal	Generis Farmacêutica, S. A. Rua João de Deus, 19 2700-487 Amadora Portugal	Levodopa/carbidop a/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/carbidop a/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/carbidop a/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/carbidop a/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/carbidop a/entacapone	Levodopa + Carbidopa + Entacapona Generis	150 mg/37,5 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	Levodopa/carbidopa/entacapone	Levodopa + Carbidopa + Entacapon 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 + Entacapon Generis	200 mg/50 mg/200 mg	Film - coated tablet	Oral use
Portugal	Generis Farmacêutica, S. A. Rua João de Deus, 19 2700-487 Amadora Portugal	Entacapone	Entacapon Generis	200 mg	Film - coated tablet	Oral use
Portugal	Labesfal, Genéricos, S.A. Av. Dr. Afonso Costa, nº 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, nº 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, nº 1370 3465-051 Campo de Besteiros Portugal	Alendronic acid	Ácido alendrónico Labesfal	70 mg	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	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 Esqº 1499-016 Algés Portugal	Donepezil	Donepezilo Anova	10 mg	Orodispersible tablet	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	20 mg	Gastro - resistant capsule, hard	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	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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 OPF United Kingdom	Cefpodoxime	Cefpodoxima Lupin	200 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	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

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	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
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

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	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
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

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	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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Pharmakern Portugal - Produtos Farmacêuticos, Sociedade Unipessoal, Lda. Edifício Atlas II, Av. José Gomes Ferreira, N.º 11 - 3º, 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 - 6º 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 - 6º 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 comprimato filmate	5 mg	Film - coated tablet	Oral use
Romania	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	SAVANDRA 10 mg comprimato filmate	10 mg	Film - coated tablet	Oral use
Romania	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	SAVANDRA 15 mg comprimato filmate	15 mg	Film - coated tablet	Oral use
Romania	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	SAVANDRA 20 mg comprimato 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, 500mg, 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, 1000 mg, comprimate filmate	1000 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

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 20 mg capsule gastrorezistente	20 mg	Gastro - resistant capsule, hard	Oral use
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 Genericsl 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

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 4 mg comprimate	4 mg	Tablet	Oral use
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 orrodispersabile	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 orrodispersabile	10 mg	Orodispersible tablet	Oral use
Romania	Glenmark Pharmaceuticals s.r.o. Hvězdova 1716/2b 14078 Praha 4 Czech Republic	Trimetazidine	Apstar 35mg Comprimate cu eliberare prelungită	35 mg	Modified - release tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
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	ENTTANIDA 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

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 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
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/hydroch lorothiazide	Irbesartan Torrent Hidrochlorotiazida 150/12,5mg 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/hydroch lorothiazide	Irbesartan Torrent Hidrochlorotiazida 300/12,5mg comprimate filmate	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
Romania	Torrent Pharma SRL Str. Stirbei Voda nr. 36 et. 2, biroul A, sector 1 Bucharest Romania	Irbesartan/hydroch lorothiazide	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
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 orodispergovateľné 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 orodispergovateľné tablety	10 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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 predĺženým uvoľňovaním	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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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 gastrorezistentne 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 gastrorezistentne 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 orodisperzibilne 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 orodisperzibilne tablete	10 mg	Orodispersible tablet	Oral use
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	Accord Healthcare, S.L.U. Moll de Barcelona s/n. World Trade Center. Edifici Est 6ª 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	DESLORATADINA 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/hydrochl orothiazide	VALSARTAN/HIDROCLORO TIAZIDA 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/hydrochl orothiazide	VALSARTAN/HIDROCLORO TIAZIDA 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/hydrochl rothiazide	VALSARTAN/HIDROCLORO TIAZIDA CODRAMOL 320/12.5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	320 mg/12,5 mg	Film - coated tablet	Oral use
Spain	Farmalider, S.A. Aragoneses 15 28108 Madrid Spain	Valsartan/hydrochl rothiazide	VALSARTAN/HIDROCLORO TIAZIDA CODRAMOL 320/25 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	320 mg/25 mg	Film - coated tablet	Oral use
Spain	Farmalider, S.A. Aragoneses 15 28108 Madrid Spain	Valsartan/hydrochl rothiazide	VALSARTAN/HIDROCLORO TIAZIDA CODRAMOL 80/12.5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA 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	DESLORATADINA 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	DESLORATADINA FLAS COMBIX 5 mg COMPRIMIDOS BUCODISPERSABLES EFG	5 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 10 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	10 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 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 PI Barcelona 08007 Spain	Alendronic acid	ACIDO ALENDRONICO SEMANAL RANBAXY 70 mg COMPRIMIDOS EFG	70 mg	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, 5º Planta 8038 Barcelona Spain	Donepezil	DONEPEZILO FLAS MYLAN PHARMACEUTICALS 10 mg COMPRIMIDOS BUCODISPERSABLES 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 COMPRIMIDOS BUCODISPERSABLES EFG	5 mg	Orodispersible tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L. Plom 2-4, 5º Planta 8038 Barcelona Spain	Esomeprazole	ESOMEPRAZOL MYLAN 20 mg CAPSULAS GASTRORRESISTENTES EFG	20 mg	Gastro - resistant capsule	Oral use
Spain	Mylan Pharmaceuticals, S.L. Plom 2-4, 5º Planta 8038 Barcelona Spain	Esomeprazole	ESOMEPRAZOL MYLAN 40 mg CAPSULAS GASTRORRESISTENTES EFG	40 mg	Gastro - resistant capsule	Oral use
Spain	Mylan Pharmaceuticals, S.L. Plom 2-4, 5º 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, 5º Planta 8038 Barcelona Spain	Repaglinide	REPAGLINIDA MYLAN 1 mg COMPRIMIDOS EFG	1 mg	Tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L. Plom 2-4, 5º Planta 8038 Barcelona Spain	Repaglinide	REPAGLINIDA MYLAN 2 mg COMPRIMIDOS EFG	2 mg	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, 5º Planta 8038 Barcelona Spain	Rizatriptan	RIZATRIPTAN MAX MYLAN 10 mg COMPRIMIDOS BUCODISPERSABLES EFG	10 mg	Orodispersible tablet	Oral use
Spain	PENSA PHARMA, S.A.U Jorge Comín (médico pediatra) 3 - bajos 46015– Valencia (Valencia) Spain	Alendronic acid	ACIDO ALENDRONICO SEMANTAL PENSA 70 mg COMPRIMIDOS EFG	70 mg	Tablet	Oral use
Spain	Pharmagenus, S.A., Avda. Camí Real, 51-57, 08184 Palau-solita i Plegamans (Barcelona) Spain	Desloratadine	DESLORATADINA PHARMAGENUS 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 (Barcelona) Spain	Desloratadine	DESLORATADINA PHARMAGENUS 5 mg COMPRIMIDOS BUCODISPERSABLES 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	DESLORATADINA TEVA 5 mg COMPRIMIDOS 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	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan	IRBESARTAN/HIDROCLOROTIAZIDA 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/HIDROCLOROTIAZIDA WELDING 300 mg/12.5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	300 mg/12,5 mg	Film - coated tablet	Oral use
Spain	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan	IRBESARTAN/HIDROCLOROTIAZIDA 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 hydrochloride	Clindamycin Alternova	150 mg	Capsule, hard	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
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

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	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
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

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	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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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, filmomhulde 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 filmomhulde tabletten	0,25 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 0,5 mg filmomhulde tabletten	0,5 mg	Film - coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirol Accord 1 mg filmomhulde 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 filmomhulde 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 10mg 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 70mg 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	Metoclopramidemonohydro chloride 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

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 250 mg, filmomhulde tabletten	250 mg	Film - coated tablet	Oral use
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/hydrochl orothiazide	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/hydrochl orothiazide	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/hydrochl orothiazide	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 capsules met verlengde afgifte, hard	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
The Netherlands	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Venlafaxine	Venlafaxine Fair-Med 75 mg capsules met verlengde afgifte, hard	75 mg	Prolonged - release capsule, hard	Oral use
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, maagsapresistente 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, maagsapresistente 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

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	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
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

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	Clonazepam	Clonazepam TioFarma 0,5 mg tabletten, 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 tabletten, 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, tabletten	10 mg	Tablet	Oral use
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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/hydroch lorothiazide	Irbesartan Hydrochloorthiazide 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/hydroch lorothiazide	Irbesartan Hydrochloorthiazide 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/hydroch lorothiazide	Irbesartan Hydrochloorthiazide Torrent 300 mg/25 mg filmomhulde tabletten	300 mg/25 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 150 mg filmomhulde tabletten	150 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 300 mg filmomhulde tabletten	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 0.25mg 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 0.5mg 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 1mg film-coated tablets	1 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 2mg 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
United Kingdom	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Alendronic acid	alendronic acid 10mg 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 70mg 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 10mg 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 5mg 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 50mg 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 150mg 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 200mg capsules	200 mg	Capsule, hard	Oral use
United Kingdom	Auden McKenzie Limited McKenzie House Bury Street, Ruislip Middlesex HA4 7TL United Kingdom	Dexamethasone	Dexamethasone 2mg Tablets	2 mg	Tablet	Oral use
United Kingdom	Auden McKenzie Limited McKenzie House Bury Street, Ruislip Middlesex HA4 7TL United Kingdom	Thiamine hydrochloride	Tyvera 50mg Tablets	50 mg	Tablet	Oral use
United Kingdom	Auden McKenzie Limited McKenzie House Bury Street, Ruislip Middlesex HA4 7TL United Kingdom	Thiamine hydrochloride	Tyvera 100mg 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 500mcg Tablet	0,5 mg	Tablet	Oral use
United Kingdom	Auden McKenzie Limited McKenzie House Bury Street, Ruislip Middlesex HA4 7TL United Kingdom	Clonazepam	Clonazepam 2mg Tablet	2 mg	Tablet	Oral use
United Kingdom	Auden McKenzie Limited McKenzie House Bury Street, Ruislip Middlesex HA4 7TL United Kingdom	Clobazam	CLOBAZAM AUDEN 10mg TABLETS	10 mg	Tablet	Oral use
United Kingdom	Brown & Burk UK, Ltd. 5, Marrayat Close Hounslow TW4 5DQ Middlesex United Kingdom	Phenoxymethyl penicillin	Phenoxymethylpenicillin 250mg Film-coated Tablets	250 mg	Film - coated tablet	Oral use
United Kingdom	Brown & Burk UK, Ltd. 5, Marrayat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram oxalate	Escitalopram 5mg 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 10mg 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 15mg 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 20mg 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	Aceon 100mg 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	Aceon 150mg Prolonged- release tablets	150 mg	Prolonged - release 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, Marrayat Close Hounslow TW4 5DQ Middlesex United Kingdom	Tramadol hydrochloride	Aceon 200mg Prolonged- release tablets	200 mg	Prolonged - release tablet	Oral use
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Valsartan	Valsartan 40mg 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 80mg 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 160mg 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 320mg Capsules	320 mg	Capsule	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 250mg 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 500mg 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 750mg film-coated tablets	750 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 1000mg film-coated tablets	1000 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 15mg Tablets	15 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	Pioglitazone	Pioglitazone 30mg 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 45mg 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 200mg 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 20mg 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 40mg 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 80mg 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 40mg/12.5mg 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 80mg/12.5mg 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 80mg/25mg Tablets	80 mg/25 mg	Tablet	Oral use
United Kingdom	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	irbesartan	Irbesartan 75mg Film-coated Tablets	75 mg	Film - coated tablet	Oral use
United Kingdom	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	irbesartan	Irbesartan 150mg Film-coated Tablets	150 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	Irbesartan 300mg Film-coated Tablets	300 mg	Film - coated tablet	Oral use
United Kingdom	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan/hydrochlorothiazide	Irbesartan/Hydrochlorothiazide 150mg/12.5mg 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 300mg/12.5mg 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 300mg/25mg 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 150mg 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 120mg 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	Fannin (UK) Ltd 42-46 Booth Drive Park Farm South Wellingborough Northamptonshire NN8 6GT United Kingdom	Fexofenadine	Fexofenadine 180mg film-coated tablets	180 mg	Film - coated tablet	Oral use
United Kingdom	FDC Pharma Unit 6, Fulcrum 1, Solent Way Whiteley, Fareham Hampshire PO15 7FE United Kingdom	Amlodipine	Amlodipine 5mg 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 10mg Tablets	10 mg	Tablet	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Repaglinide	Repaglinide Mylan 0.5mg Tablets	0,5 mg	Tablet	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Repaglinide	Repaglinide Mylan 1mg Tablets	1 mg	Tablet	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Repaglinide	Repaglinide Mylan 2mg Tablets	2 mg	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	Donepezil hydrochloride	Donepezil Hydrochloride 5mg Orodispersible Tables	5 mg	Orodispersible tablet	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Donepezil hydrochloride	Donepezil Hydrochloride 10mg Orodispersible Tables	10 mg	Orodispersible tablet	Oral use
United Kingdom	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Rizatriptan benzoate	Rizatriptan 10mg 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 20mg 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 40mg 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/carbidop a/entacapone	Levodopa/Carbidopa/Entac apone film-coated tablets 150/37.5/200mg	150 mg/37,5 mg/200 mg	Film - coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 OPF United Kingdom	Pantoprazole	Pantoprazole 20mg Gastro-Resistant tablets	20 mg	Gastro - resistant tablet	Oral use
United Kingdom	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 OPF United Kingdom	Pantoprazole	Pantoprazole 40mg Gastro-Resistant tablets	40 mg	Gastro - resistant tablet	Oral use
United Kingdom	Morningside Healthcare Limited 115 Narborough Road Leicester, LE3 OPA United Kingdom	Phenoxymethyl penicillin	Phenoxymethylpenicillin 250mg Film-coated Tablets	250 mg	Film - coated tablet	Oral use
United Kingdom	Morningside Healthcare Limited 115 Narborough Road Leicester, LE3 OPA United Kingdom	Metformin hydrochloride	Bolamyn/Metabet SR 1000mg Prolonged Release Tablets	1000 mg	Prolonged - release tablet	Oral use
United Kingdom	Niche Generics Limited 1 The Cam Centre Wilbury Way, Hitchin Hertfordshire SG4 OTW United Kingdom	irbesartan	Irbesartan Niche 150mg film-coated tablets	150 mg	Film - coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Niche Generics Limited 1 The Cam Centre Wilbury Way, Hitchin Hertfordshire SG4 0TW United Kingdom	irbesartan	Irbesartan Niche 150mg 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 70mg Tablets	70 mg	Tablet	Oral use
United Kingdom	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydrochlorothiazide	Irbesartan Hydrochlorothiazide 150mg/12.5mg 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 300mg/12.5mg Film-coated tablets	300 mg/12,5 mg	Film - coated tablet	Oral use
United Kingdom	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	Irbesartan/hydrochlorothiazide	Irbesartan Hydrochlorothiazide 300mg/25mg Film-coated tablets	300 mg/25 mg	Film - coated tablet	Oral use
United Kingdom	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	irbesartan	Irbesartan 75mg Film-coated tablets	75 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	Irbesartan 150mg Film-coated tablets	150 mg	Film - coated tablet	Oral use
United Kingdom	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg Germany	irbesartan	Irbesartan 300mg Film-coated tablets	300 mg	Film - coated tablet	Oral use
United Kingdom	Waymade PLC Sovereign House Miles Grat Road, Basildon Essex SS14 3FR United Kingdom	Venlafaxine hydrochloride	Venlasov XL 75mg Modified Release Capsules	75 mg	Prolonged - release capsule, hard	Oral use
United Kingdom	Waymade PLC Sovereign House Miles Grat Road, Basildon Essex SS14 3FR United Kingdom	Venlafaxine hydrochloride	Venlasov XL 150mg Modified Release Capsules	150 mg	Prolonged - release capsule, hard	Oral use
United Kingdom	Wockhardt UK Limited Ash Road North Wrexham Industrial Estate Wrexham LL13 9UF United Kingdom	Clopidogrel	Clopidogrel 75mg 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 10mg Tablets	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	YJBPort Limited 74 Briarwood Drive Northwood Hills Middlesex HA6 1PL United Kingdom	Hydrocortisone	Hydrocortisone 20mg Tablets	20 mg	Tablet	Oral use

Annex II

Scientific conclusions and grounds for the recommendations for maintenance and suspension of the marketing authorisations

Scientific conclusions

Overall summary of the scientific evaluation

The French Agency on medicinal products (ANSM) conducted an inspection on 19-23 May 2014 (inspection reference GCP-141001-FR) at GVK Biosciences Private Limited, Swarna Jayanthi commercial complex, Ameerpet, Hyderabad 500 038, India. For the purpose of this report, GVK Biosciences Private Limited/Clinogent will be hereafter referred to as 'GVK Bio'.

The following findings were reported in the French inspection report dated 02 July 2014, to which GVK Bio have responded on 18 July 2014 and in the final inspection report, which was issued on 21 July 2014: data manipulations of electrocardiograms (ECGs) were detected in each and every one of the 9 trials inspected by the ANSM. These data manipulations cast doubts on the authenticity of all other clinical records of these nine clinical trials. They were therefore considered by the ANSM as not compliant with Good Clinical Practice (GCP) and were considered not reliable to support marketing authorisation applications (MAAs). The data manipulations took place between at least July 2008 and 2013. The systematic nature of the data manipulations of ECGs, the extended period of time during which they took place and the number of members of staff involved highlight critical deficiencies in the quality system in place at GVK Bio's clinic in Hyderabad. They also show a lack of GCP training, awareness and understanding of members of GVK Bio staff, a lack of understanding by them of the importance of data integrity and of the possible consequences of their acts, as well as a lack of overview of clinical trial activities by the investigators.

The seriousness of the deficiencies identified and the lack of GCP compliance at GVK Bio's clinic in Hyderabad raise questions as to the reliability of studies conducted between 2008 and 2014 at the site inspected, as well as the clinical part of all other bioequivalence trials performed prior to 2008.

The European Commission initiated a referral under article 31 of Directive 2001/83/EC on 4 August 2014. The CHMP was asked to assess the potential impact of the findings on the benefit risk balance of products authorised on the basis of studies with clinical activities performed at the inspection site. The medicinal products concerned are listed in Annex I.

Discussions

The procedure started on 25 September 2014. During September 2014 CHMP plenary meeting, the CHMP adopted a LoQ to the CRO to clarify whether the findings should be confined to the period 2008-2014, to specific clinical trials and/or specific clinical activities at the Hyderabad site.

During the November 2014 meeting, after GVK Biosciences' submission of responses as well as providing information relating to the matter before the CHMP on 22 October 2014, the CHMP determined that GVK Biosciences Pvt. Ltd. did not provide evidence to demonstrate that the problem was confined to a specific time period or specific clinical trials or specific individuals and clinical activities. The CHMP therefore concluded that all bioequivalence studies with clinical activities carried out at GVK Biosciences Pvt. Ltd. site in Hyderabad, India, since GVK Biosciences Pvt. Ltd. started these activities in 2004 are considered unreliable to support the benefit risk balance of the medicinal products they relate to. The CHMP therefore decided to extend the scope of the review by also including studies performed between 2004 and 2008. A list of questions to MAHs was adopted to request them to submit data to prove bioequivalence for their medicinal products vis-à-vis the EU reference medicinal product, as appropriate.

Following submission of MAHs' responses, and whilst due consideration was given to every MAHs' replies, the arguments and data provided were classified into three categories.

- Category 1: No new biowaiver request or data to establish the bioequivalence vis-à-vis the EU reference medicinal product (apart from BE studies conducted at GVK Biosciences Hyderabad site)
- Category 2: New biowaiver request submitted
- Category 3: New bioequivalence vis-à-vis the EU reference medicinal product study submitted

Discussions on the above took place during the December 2014 CHMP plenary meeting during which the CHMP endorsed the above mentioned classification.

Considerations to all products reviewed within the framework of this procedure

Where the bioequivalence is not established, safety and efficacy cannot be extrapolated from the EU reference medicinal product to the generic product as the bioavailability of the active substance between the two medicinal products may differ. If the bioavailability of the product was higher than the bioavailability of the reference medicinal product, this would result in a higher than intended exposure of patients to the active substance, leading potentially to an increase in the incidence or severity of the adverse effects. If the bioavailability of the product was lower than the bioavailability of the reference medicinal product, this would result in a lower than intended exposure of patients to the active substance, leading potentially to a decrease in efficacy, a delay or even a lack of therapeutic efficacy.

Taken into account the above, the benefit-risk balance of the medicinal product where the bioequivalence is not established is not positive as it cannot be excluded that it would lead to safety/tolerability or efficacy issues.

In addition to the submitted studies, some MAHs have highlighted that some audits and inspections with a positive outcome were carried out at GVK Biosciences Pvt. Ltd. facility in Hyderabad, India, and argued that, in view of this, the bioequivalence studies conducted at the site can be relied upon as sufficient to support a Marketing Authorisation. However, in light of the nature, the severity and the extent of the GCP findings identified in the ANSM's inspection in May 2014, these arguments do not demonstrate that the said studies can be relied upon. Indeed, any mentioned audits and inspections, including those that have been done at the site since the GCP findings by the ANSM's inspection, do not provide sufficient reassurance since they may not have detected serious GCP violations, even if present. Hence, the CHMP cannot rule out beyond reasonable doubt that critical GCP violations at the site have affected the said studies. Therefore the CHMP is of the opinion that the studies cannot be relied upon to establish bioequivalence vis-à-vis the EU reference medicinal product.

The plausibility of results and controls of data integrity by MAHs were not considered sufficient to establish the bioequivalence based on studies performed at GVK Bio-Hyderabad site and therefore acceptable as basis for a marketing authorisation.

A number of MAHs have also argued that pharmacovigilance data collected on their medicinal products have not indicated any problems, which could be attributed to non-bioequivalence, such as reduced efficacy or worsened safety and tolerability. However, the CHMP is of the opinion that the absence of the identification of any pharmacovigilance signals does not provide sufficient reassurance because it is not established that the pharmacovigilance activities may be designed to detect such a signal.

Some MAHs have provided results from bioequivalence data using non-EU Reference Medicinal Products. According to article 10 of Directive 2001/83/EC, the bioequivalence vis-à-vis an EU reference medicinal product needs to be established and therefore the abovementioned studies can not be considered fulfilling the criteria of article 10.

Some MAHs have submitted bioequivalence data from a study associated with unresolved, critical GCP findings. The CHMP concluded that the critical GCP findings did not allow these studies to be relied upon to establish the bioequivalence vis-à-vis the EU reference medicinal product.

Category 1 medicinal products

The category encompasses products for which MAHs have not provided any biowaiver request or bioequivalence study vis-à-vis the EU reference medicinal product generated elsewhere than at GVK Biosciences Pvt. Ltd. facility in Hyderabad, India, or where MAHs have not responded. Nevertheless many MAHs provided miscellaneous statements, as described in the previous section, concerning benefit risk balance of the medicinal products. These statements were carefully assessed.

In conclusion, in the absence of demonstration of the bioequivalence vis-à-vis the EU reference medicinal product, the CHMP concluded that the efficacy and safety of the concerned category 1 medicinal product can not be established, and hence the benefit-risk balance cannot be considered positive.

Category 2 medicinal products

This category encompasses medicinal products for which MAHs have provided biowaiver request (i.e. claims to fulfil the criteria for a Biopharmaceutics Classification System (BCS)-based biowaiver as described in Appendix III of the Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98) to establish bioequivalence to an EU Reference Medicinal Product.

For products of Annex IA containing Levetiracetam, Levocetirizine and Metoclopramide, the CHMP considers that the biowaiver request is acceptable. The bioequivalence is therefore established and the benefit-risk balance for these products remains positive. The CHMP recommends therefore the maintenance of the concerned marketing authorisations.

For the remaining medicinal products in category 2 (i.e. products of Annex IB containing Donepezil), the following issues precluding the establishment of bioequivalence to an EU Reference Medicinal Product were raised:

- Absorption through the oral cavity for an orodispersible formulation cannot be excluded
- Composition differences – the test product contains critical excipients that may affect the pharmacokinetics profile of the medicinal product (absorption).

In the absence of the demonstration of bioequivalence vis-à-vis the EU reference medicinal product, the efficacy and safety of these medicinal products can not be established, and hence the benefit-risk balance cannot be considered positive. The CHMP recommends therefore the suspension of the concerned marketing authorisations.

Category 3 medicinal products

This category encompasses products for which MAHs have provided data from other bioequivalence studies vis-à-vis the EU reference medicinal product than the one performed at GVK Biosciences Pvt. Ltd.'s site in Hyderabad, India.

For the following medicinal products in category 3 (products of Annex IA containing Bendroflumetiazid Bosentan, Fexofenadine, Lansoprazole, Nebivolol and Venlafaxine), the CHMP is of the opinion that the results of the provided trials establish the bioequivalence vis-à-vis the EU reference medicinal product. The benefit-risk balance for these medicinal products remains therefore positive. The CHMP recommends therefore the maintenance of the concerned marketing authorisations.

For the remaining medicinal products in category 3 (products of Annex IB containing Clindamycin, Esomeprazole, Phenoxymethylpenicillin, Trimetazidine), the issues precluding the establishment of bioequivalence to an EU Reference Medicinal Product pertain to:

- The identity of test product in the study with the authorized (marketed) product is not clear.
- The full study report of the bioequivalence study is missing, only a study synopsis has been submitted.
- The reference product is not authorized in the EU.
- The steady state study for a modified release product is missing.
- The single-dose study for a modified release product is missing.
- Only a synopsis of a pilot study has been submitted.
- The test product was expired at the time of study.
- The full bioanalytical report is missing.
- A biowaiver for a lower strength is not acceptable, as comparative dissolution according to bioequivalence guideline were not submitted.

Further to the assessment, the CHMP noted that medicinal products containing Pravastatin were to be excluded of this procedure as out of the scope of the procedure.

Benefit-risk balance

Having taken into account the ANSM's inspection report, the available data and all arguments presented in the MAHs' replies, the CHMP concluded in its plenary meeting on January 2015 that in the absence of demonstration of bioequivalence to an EU Reference Medicinal Product, the efficacy, safety and tolerability of the concerned medicinal product cannot be established.

Indeed, where the bioequivalence is not established, the efficacy, safety and tolerability cannot be extrapolated from the reference medicinal product to the generic product as the bioavailability of the active substance between the two medicinal products may differ. If the bioavailability of the product was higher than the bioavailability of the reference medicinal product, this would result in a higher than intended exposure of patients to the active substance, leading potentially to an increase in the incidence or severity of the adverse effects. If the bioavailability of the product was lower than the bioavailability of the reference medicinal product, this would result in a lower than intended exposure of patients to the active substance, leading potentially to a decrease in efficacy, a delay or even a lack of therapeutic efficacy. In the light of these uncertainties and consequent potential efficacy, safety and tolerability concerns, the benefit-risk balance of the concerned medicinal products is not positive.

The following conclusions were adopted by CHMP accordingly based on the assessment of the MAHs' replies and after having given due consideration to all arguments presented by MAHs:

- For medicinal products (Annex IA) for which other bioequivalence studies than the one(s) performed at GVK Biosciences Hyderabad site or claims that the medicinal products fulfil the criteria for a Biopharmaceutics Classification System (BCS)-based biowaiver as described in Appendix III of the Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98) were submitted, assessed and considered positive by the CHMP (i.e. medicinal products containing Bendroflumetiazid, Bosentan, Fexofenadine, Lansoprazole, Levetiracetam, Levocetirizine, Metoclopramide, Nebivolol and Venlafaxine), the CHMP is of the opinion that the bioequivalence has been established.

The benefit-risk balance for the products of Annex IA remains positive and the CHMP recommends therefore the maintenance of the concerned marketing authorisations.

- With regards to medicinal products (Annex IB) for which bioequivalence data was not submitted or considered insufficient by the CHMP to support a positive benefit risk balance of the concerned medicinal products, the CHMP is of the opinion that the bioequivalence with an EU authorised reference medicinal product has not been established and therefore concluded that the particulars supporting the marketing authorisation are incorrect and that the benefit-risk balance of the concerned medicinal products is not positive as pursuant to Article 116 of Directive 2001/83/EC.

The Committee therefore recommends that these marketing authorisations (Annex IB) should be suspended unless the medicinal product is considered critical by the relevant national competent authorities. For marketing authorisation(s) of a medicinal product considered critical, the suspension may be deferred in the relevant Member State(s) for a period which shall not exceed twenty-four months from the Commission Decision. Should during this period the Member State(s) consider a medicinal product not critical anymore, the suspension of the concerned marketing authorisation shall apply.

For these medicinal products considered critical by Member States, the marketing authorisations holders shall submit a bioequivalence study conducted vis-à-vis the EU Reference Medicinal Product within 12 months following Commission Decision.

A medicinal product listed in Annex IB may be considered critical by the Member State(s) based on the evaluation of the potential unmet medical need, considering the availability of suitable alternative medicinal products in the respective Member State(s) and, as appropriate, the nature of the disease to be treated.

For marketing authorisations recommended for suspension, the CHMP concluded the suspension could be lifted when bioequivalence to an EU Reference Medicinal Product has been established based on a bioequivalence study conducted vis-à-vis the EU Reference Medicinal Product.

Re-examination procedure

Following the adoption of the CHMP opinion during the January 2015 CHMP meeting, requests for re-examination were received from the following MAHs:

1. Ranbaxy, Basics GmbH, Takeda Belgium, Pensa Pharma and Labesfal Genéricos (for Alendronate);
2. Heumann Pharma GmbH & co. Generica KG, and Torrent Pharma GmbH / Torrent Pharma SRL (for Irbesartan hydrochlorothiazide and Irbesartan);
3. Dr. Reddy's Laboratories (UK) Ltd and betapharm Arzneimittel GmbH (for Dipyridamole and Levetiracetam);
4. Neo Balkanika (for Nebivolol);
5. Genericon Pharma Austria (for Nebivolol).

In support of their request for re-examination, MAHs submitted grounds to argue that the benefit risk balance of their products subject to a suspension of MA is positive. The grounds submitted were taken into consideration and assessed by the CHMP.

The CHMP conclusions on the points raised in the MAH's grounds are given below.

- **Request for re-examination for Alendronate:**

Importance of alendronate therapy for patients: The MAHs argue on the importance of the alendronate therapy for patients and continuous availability of the medicine to safeguard public health.

It is recognised that alendronate occupies an important place in the treatment of post-menopausal osteoporosis. However, prescription of the suspended MAs can be reported to another generic or the innovator brand. In addition, reference is made to the CHMP opinion in which it is stated that individual Member States may consider medicinal products critical based on the evaluation of the potential unmet medical need, considering the availability of suitable alternative medicinal products in the respective Member State(s) and, as appropriate, the nature of the disease to be treated. Where on the basis of these criteria the relevant national competent authorities of the Member States consider that a medicinal product is critical, the suspension of the concerned marketing authorisation(s) may be deferred by the period for which the medicinal product is considered critical (period which can not exceed twenty-four months from the Commission Decision).

The CHMP is of the view that this argument does not substitute the need to establish bioequivalence with an EU reference medicinal product in order to conclude on the positive benefit-risk balance of the concerned medicinal products.

Not all phases of the study performed at GVK Bio: For the original submission, the MAH had conducted a bioequivalence study that compared its test product Alendronate Sodium 70 mg Tablets with the European innovator, Fosamax 70 mg tablets in healthy, adult, male, human subjects under fasting condition. The clinical phase was conducted at GVK Bio; the bioanalytical, pharmacokinetic and statistical phases of the study were carried out by another CRO.

Serious findings were identified at the clinical site where the study was carried out, and in view of the seriousness of the deficiencies identified, the obtained data at the clinical site are considered not reliable by the CHMP. Therefore the CHMP is of the view that analysing the plasma samples at another CRO cannot overcome the fact that the generated data are unreliable.

The CHMP is of the view that the argument presented by the MAHs above does not substitute the need to establish bioequivalence with an EU reference medicinal product in order to conclude on the positive benefit-risk balance of the concerned medicinal products and therefore should be rejected.

Submission of new scientific data: The MAHs informed the CHMP that they have initiated activities for a new bioequivalence study. The information was noted, but as no data of this bioequivalence study have been submitted within the article 31 procedure, it was not considered in the review.

Therefore the MAH still needs to establish bioequivalence with the EU reference medicinal product in order to conclude on the positive benefit-risk balance of the medicinal product.

Post-marketing experience: The MAH argues on the long term post marketing experience of almost seven years for Alendronic acid containing formulations.

The CHMP noted that pharmacovigilance data reported to the competent authorities have not indicated any problems which could be attributed to non-bioequivalence, such as reduced efficacy or worsened safety and tolerability. However, the CHMP considers that the pharmacovigilance activities may likely have lacked the ability to detect a signal with regard to efficacy or safety and tolerability, and the lack of any pharmacovigilance signal does not offer sufficient reassurance to conclude on a positive benefit risk in the absence of the demonstration of bioequivalence with the EU reference medicinal product.

Finally, it is noted that bioequivalence for a generic product should be proven in line with the criteria as outlined in article 10 of Directive 2001/83/EC and the Guideline on the investigation of bioequivalence.

For the above reasons, the lack of proof of bioequivalence can not be substituted by post marketing experience data.

- **Request for re-examination for Irbesartan and Irbesartan hydrochlorothiazide:**

BE established versus non-EU RMP for Irbesartan: For the EU MA dossier for Irbesartan 75, 150 and 300 mg tablets, the following bioequivalence study has been performed: bioequivalence study for Irbesartan Film-coated Tablets using 300mg strength against EU reference product APROVEL 300 mg Film-coated Tablets. Subsequently, for Australian (AU) generic dossier submission, a bioequivalence study was performed using Irbesartan Film-coated Tablets 300 mg against the AU reference product AVAPRO 300mg Film-coated Tablets sourced from the Australian market.

The MAH claims that the data obtained in the AU study are still applicable for the EU. In addition, the MAH claims that in art 10 of Directive 2001/83/EC there is 'room for interpretation', and it is not specifically mentioned that an EU reference product must be used. According to the MAH, this is only mentioned in the Guideline on the Investigation of Bioequivalence. Finally, the MAH states that repeating the bioequivalence study would result in confirming what the MAH already knows, i.e. that the test Irbesartan product is bioequivalent with the EU reference product. That being the case, volunteers would be unnecessarily exposed to a medicinal product without a clear need, which is not acceptable from an ethical point of view.

For generic products authorised under Article 10(1) of Directive 2001/83/EC, establishment of bioequivalence vis-à-vis a reference medicinal product is a pre-requisite. This reference medicinal product has to be authorised in the EU under the EU procedures described in Article 6 and in accordance with the EU requirements defined in Article 8 of the said Directive.

Without prejudice to the above requirement, the CHMP reviewed the MAHs argumentation and considered from a scientific perspective that it is not established with the provided data that both AU and EU reference medicinal products are identical (e.g., the manufacturing sites are unknown, the quantitative compositions are unknown).

The provided study does not establish the bioequivalence with a reference medicinal product authorised in the EU. In conclusion, the CHMP is of the view that the data submitted by the MAHs are not suitable to support the positive benefit-risk balance of the medicinal product.

BE established versus non-EU RMP for Irbesartan hydrochlorothiazide: For the EU MA dossier for Irbesartan/hydrochlorothiazide 150 mg/12.5 mg, 300 mg/12.5 mg and 300 mg/25 mg the following bioequivalence study has been performed: bioequivalence study for Irbesartan + Hydrochlorothiazide Film-coated Tablets using 300/25mg strength against EU reference product COAPROVEL 300/25mg Filmcoated Tablets. Subsequently, for AU generic dossier submission, a bioequivalence study was performed using Alembic's Irbesartan Hydrochlorothiazide Film-coated Tablets 300mg/25 mg against the AU reference product AVAPRO HCT 300mg Film-coated Tablets sourced from Australian market.

Based on the same argumentation as described above for Irbesartan, the MAH claims that the data obtained in the AU study are still applicable for the EU. Having considered the MAHs' argumentation, the CHMP confirms its opinion and concludes that the data submitted by the MAHs are not suitable to support the positive benefit-risk balance of the medicinal product.

- **Re-examination request for Levetiracetam and Dipyridamole:**

New scientific data: The MAHs have submitted a biowaiver request for levetiracetam and a new bioequivalence study for dipyridamole. The MAHs did not submit the above mentioned scientific data before the adoption of the initial opinion.

As stated in Article 62(1) paragraph 4 of Regulation (EC) No 726/2004 and Article 32(4) paragraph 3 of Directive 2001/83/EC, *"the re-examination procedure may deal only with the points of the opinion initially identified by the applicant/MAH and may be based only on the scientific data available when the Committee adopted the initial opinion."* Therefore these scientific data can not be considered during the re-examination procedure.

Positive inspection and audit history of the GVK Bio Hyderabad site: The MAHs argue that based on the fact that a GCP audit by the MHRA of a study conducted at the site failed to identify any critical or major breaches of GCP, the CHMP conclusions that studies conducted at GVK Bio facility cannot be relied upon to demonstrate bioequivalence cannot be justified. The MAHs also state that they note the opinion regarding GCP audits conducted by GVK Bio's clients (i.e. implying that these audits were substandard as they did not identify any serious violations of GCP at the GVK Bio facility). The MAHs argue that this generalisation can only be justified if evidence is provided that individual audits were not conducted to the appropriate standard, and that no such evidence has been provided.

The CHMP acknowledges that a number of audits by GVK's clients and inspections by competent authorities were carried out at GVK Bio-Hyderabad over a large period without identifying critical findings. However the CHMP is of the view that the findings by ANSM in 2014 were serious in terms of the impact on the integrity of the studies.

The results and controls of data integrity by MAHs were not considered sufficient to override the findings of the ANSM inspection at GVK Bio-Hyderabad site.

In addition, inspections by regulatory authorities follow a sampling process in which specific parts of a particular activity are looked at in detail to establish whether its conduct complied with all relevant guidelines and regulations. This means that a successful outcome in a particular inspection cannot be taken as a guarantee that all processes are properly run and GCP compliant. Nor does it allow for the findings of a previous inspection to be ignored.

Finally, The CHMP determined that GVK Bio did not provide evidence to demonstrate that the problem was confined to a specific time period or specific clinical trials or specific individuals and clinical activities. The CHMP therefore concluded that all bioequivalence studies with clinical activities carried

out at GVK Bio site in Hyderabad, India, since GVK Bio started these activities in 2004 are considered unreliable to support the benefit risk balance of the medicinal products they relate to.

The CHMP therefore confirms that it cannot be ruled out beyond reasonable doubt that critical GCP violations at the site have not affected the integrity of the scientific data of other bioequivalence studies conducted at the site, and that the studies therefore remain unreliable. The CHMP is of the opinion that these studies can not be used to establish bioequivalence with the EU reference medicinal product and therefore to support a generic marketing authorisation.

- **Re-examination request for Nebivolol Neo-Balkanika:**

The MAH claimed that it had not received the official notification of the inclusion of the product in the Article 31 Referral procedure. Therefore the information submitted at the stage of re-examination was taken into consideration in order to safeguard the right of defence of the company.

Neo-Balkanika submitted the bioequivalence study (PK-05-035) which had already been submitted during the referral procedure in support of marketing authorisations for Nebivolol 5 mg tablets, with the same qualitative and quantitative composition and same manufacturers. The CHMP had already assessed this study and concluded that it can be considered as acceptable proof of bioequivalence and the benefit risk balance of the respective marketing authorisations can be considered positive.

In conclusion, bioequivalence with an EU authorised reference medicinal product is confirmed and therefore it can be concluded that the benefit/risk balance of Nebivolol / Neo Balkanika is positive.

- **Re-examination request for Nebivolol Genericon Pharma Austria**

The MAH has submitted a bioequivalence study for Nebivolol during the course of the re-examination. The MAH did not exercise the right to submit the above mentioned scientific data for assessment before the adoption of the initial opinion.

As stated in Article 62(1) paragraph 4 of Regulation (EC) No 726/2004 and Article 32(4) paragraph 3 of Directive 2001/83/EC, *“the re-examination procedure may deal only with the points of the opinion initially identified by the applicant/MAH and may be based only on the scientific data available when the Committee adopted the initial opinion.”* Therefore these scientific data can not be considered during the re-examination procedure.

- **Overall conclusion of the re-examination**

Based on the totality of the data available, including the information submitted during the original assessment procedure and the detailed grounds for re-examination put forward by the MAHs, the CHMP:

- Concluded that the benefit risk of Nebivolol/Neo Balkanika is positive, therefore Nebivolol/Neo Balkanika is included in the list of medicinal products recommended for maintenance of the marketing authorisation;
- Confirmed its previous recommendation to suspend the marketing authorisations for medicinal products for which bioequivalence vis-à-vis the EU reference medicinal product was not established.

Grounds for CHMP Opinion

Whereas

- The Committee considered the procedure under Article 31 of Directive 2001/83/EC for medicinal products concerned by the GVK Bio procedure;
- The Committee reviewed all available data and information provided by the MAHs, as well as information provided by GVK Bio;
- The Committee considered the grounds for re-examination provided by the MAHs in writing;
- The Committee concluded in accordance with Article 116 of Directive 2001/83/EC that the particulars supporting the marketing authorisation are incorrect and that the benefit-risk balance is not positive for marketing authorisations of medicinal products for which bioequivalence data or justification was not submitted or considered insufficient by the CHMP to establish bioequivalence vis-à-vis the EU reference medicinal product (Annex IB);
- The Committee concluded for marketing authorisations of medicinal products of Annex IA containing Bendroflumetiazid, Bosentan, Fexofenadine, Lansoprazole, Levetiracetam, Levocetirizine, Metoclopramide, Nebivolol and Venlafaxine that the benefit risk balance is positive in the approved indications.

Therefore, in accordance with Articles 31 and 32 of Directive 2001/83/EC, the CHMP recommends:

- a. To suspend the marketing authorisations for medicinal products for which bioequivalence data or justification were not submitted or considered insufficient by the CHMP to establish bioequivalence vis-à-vis the EU reference medicinal product (Annex IB), as the particulars supporting the marketing authorisations are incorrect and that the benefit-risk balance of these marketing authorisation is not positive pursuant to Article 116 of Directive 2001/83/EC.

The condition for the lifting of the suspension of the Marketing Authorisations, as applicable, is set out in Annex III.

The CHMP therefore recommends by consensus the suspension of the Marketing Authorisations for the medicinal products referred to in Annex IB.

Some of these medicinal products may be considered critical by the individual Member States on the evaluation of the potential unmet medical need, considering the availability of suitable alternative medicinal products in the respective Member State(s) and, as appropriate, the nature of the disease to be treated.

Where on the basis of these criteria the relevant national competent authorities of the Member States consider that a medicinal product is critical, the suspension of the concerned marketing authorisation(s) may be deferred by the period for which the medicinal product is considered critical. This period of deferral shall not exceed twenty-four months from the Commission Decision. Should during this period the Member State(s) consider a medicinal product not critical anymore, the suspension of the concerned marketing authorisation(s) shall apply.

For these medicinal products considered critical by Member State(s), the marketing authorisations holders shall submit a bioequivalence study conducted vis-à-vis the EU Reference Medicinal Product within 12 months from the Commission Decision.

- b. To maintain the marketing authorisations for medicinal products for which the bioequivalence vis-à-vis the EU reference medicinal product has been established (Annex IA) as the benefit risk balance of these marketing authorisation is positive.

Annex III

Condition for lifting the suspension of the Marketing Authorisations

Conditions for lifting the suspension of the Marketing Authorisations

The National Competent Authorities of Member States or Reference Member States if applicable, shall ensure that the following condition is fulfilled by the MAH(s):

Suspension of the marketing authorisations should be lifted when bioequivalence to an EU Reference Medicinal Product has been established based on a bioequivalence study conducted vis-à-vis the EU Reference Medicinal Product.