

21 May 2015
EMA/344050/2015
Procedure Management and Committee Support

Products for which the marketing authorisations are recommended for suspension by the CHMP on 21 May 2015

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1408

Some of these medicinal products may be considered critical by the individual EU Member States. The suspension of the concerned marketing authorisation(s) may be deferred by the period for which the medicinal product is considered critical.

Note

The final CHMP recommendation is based on data available at the time of its initial recommendation in January 2015. If marketing authorisation holders have since submitted data from appropriate bioequivalence studies to national authorities, it is for the national authorities to decide on the maintenance of the marketing authorisations.

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 Terhulpsessesteenweg 6A 1560 Hoeilaart Belgium	Donepezil	Donepezil Odis Mylan	5 mg	Orodispersible tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpsessesteenweg 6A 1560 Hoeilaart Belgium	Donepezil	Donepezil Odis Mylan	10 mg	Orodispersible tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpsessesteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan 0,5 mg Pharma	0,5 mg	Tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpsessesteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan 1 mg Pharma	1 mg	Tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpsessesteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan 2mg Pharma	2 mg	Tablet	Oral use
Belgium	Mylan bvba/sprl Terhulpsessesteenweg 6A 1560 Hoeilaart Belgium	Candesartan	Candesartan Mylan	8 mg	Tablet	Oral use

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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Belgium	Teva Pharma Belgium NV Laarstraat 16 2610 Wilrijk Belgium	Desloratadine	Desloratadine Teva	5 mg	Orodispersible tablet	Oral use
Bulgaria	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirole Accord	0,5 mg	Film - coated tablet	Oral use
Bulgaria	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirole Accord	1 mg	Film - coated tablet	Oral use
Bulgaria	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirole Accord	2 mg	Film - coated tablet	Oral use
Bulgaria	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirole Accord	5 mg	Film - coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Bulgaria	Alkaloid - INT d.o.o. Šlandrova 4 1231 Ljubljana - Črnuče Slovenia	Cefpodoxime	FOXERO	200 mg	Tablet	Oral use
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

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

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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Croatia	Jadran Galenski Laboratorij d.d. Svilno 20, Rijeka 51000 Croatia	Desloratadine	Escontral direkt 2,5 mg raspadljiva tableta za usta	2,5 mg	Orodispersible tablet	Oral use
Croatia	Jadran Galenski Laboratorij d.d. Svilno 20, Rijeka 51000 Croatia	Desloratadine	Escontral direkt 5 mg raspadljiva tableta za usta	5 mg	Orodispersible tablet	Oral use
Croatia	PharmaS d.o.o. Radnička cesta 47 Zagreb 10000 Croatia	Tramadol/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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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/hydrochl orothiazide	Valsartan/Hctz Fair-med	160 mg/12,5 mg	Film - coated tablet	Oral use
Cyprus	Generics Pharma Hellas Ltd 577a Vouliagmenis Avenue Argyroupoli 164-51 Athens Greece	Donepezil hydrochloride	Donepezil/Generics	5 mg	Orodispersible tablet	Oral use
Cyprus	Generics Pharma Hellas Ltd 577a Vouliagmenis Avenue Argyroupoli 164-51 Athens Greece	Donepezil hydrochloride	Donepezil/Generics	10 mg	Orodispersible tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Cyprus	Lambda Therapeutic Limited Sage House 319 Pinner Road, North Harrow Middlesex HA1 4HF United Kingdom	Ropinirole hydrochloride	Ropinirole Lambda	0,25 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
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

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	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
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

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 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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Czech Republic	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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. Reykjavikurvegi 76-78 220 Hafnarfjörður Iceland	Metformin	Metformin "Actavis PTC"	500 mg	Prolonged - release tablet	Oral use
Denmark	Actavis Group PTC ehf. Reykjavikurvegi 76-78 220 Hafnarfjörður Iceland	Metformin	Metformin "Actavis PTC"	750 mg	Prolonged - release 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	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

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	Eletriptan	Eletriptan Mylan	40 mg	Film - coated tablet	Oral use
Finland	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Repaglinide	Repaglinid Mylan	0,5 mg	Tablet	Oral use
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

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	160 mg	Film - coated tablet	Oral use
Finland	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	VALSARTAN ORION	320 mg	Film - coated tablet	Oral use
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

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 15mg, comprimé pelliculé	15 mg	Film - coated tablet	Oral use
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

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 2mg, comprimé pelliculé	2 mg	Film - coated tablet	Oral use
France	ACCORD HEALTHCARE France SAS 45 Rue de Fbg de Roubaix 59000 Lille France	Ropinirole	Ropinirole Accord 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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Brown & Burk UK, Ltd. 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram	ESCITALOPRAM BROWN 20 mg, comprimé pelliculé sécable	20 mg	Film - coated tablet	Oral use
France	Brown & Burk UK, Ltd. 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Ebastine	EBASTINE BROWN & BURK 10 mg, comprimé orodispersible	10 mg	Orodispersible tablet	Oral use
France	Cristers 22, quai Galliéni 92150 Suresnes France	Desloratadine	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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Laboratoires Biogaran 15, boulevard Charles de Gaulle 92707 Colombes Cedex France	Ebastine	EBASTINE BIOGARAN 10 mg comprimé orodispersible	10 mg	Orodispersible tablet	Oral use
France	Laboratoires GERDA 24 rue Erlanger 75016 PARIS France	Desloratadine	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

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	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
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 sécable	32 mg	Tablet	Oral use
France	Mylan SAS 117 allée des Parcs 69792 Saint-Priest Cedex France	Donepezil	DONEPEZIL MYLAN 5 mg, orodispersible tablet	5 mg	Orodispersible tablet	Oral use

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	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
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

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	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
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

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

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	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
France	Zydus France Zacles Hautes Patures 25 Rue des Peupliers 92752 Nanterre Cedex France	Ibuprofen	IBUPROFENE ZF 400 mg comprimé pelliculé	400 mg	Film - coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Zydus France Zacles Hautes Patures 25 Rue des Peupliers 92752 Nanterre Cedex France	Desloratadine	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

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 160 mg/12.5 mg Filmtabletten	160 mg/12,5 mg	Film - coated tablet	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/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

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 500 mg Filmdabletten	500 mg	Film - coated tablel	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Ciprofloxacin	Ciprofloxacin Fair-Med Healthcare 750 mg Filmdabletten	750 mg	Film - coated tablel	Oral use
Germany	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Ciprofloxacin	Ciprofloxacin Fair-Med Healthcare 250 mg Filmdabletten	250 mg	Film - coated tablel	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 90449 Nürnberg Germany	Irbesartan	Irbesartan Heumann 75 mg Filmdabletten	75 mg	Film - coated tablel	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 90449 Nürnberg Germany	Irbesartan	Irbesartan Heumann 150 mg Filmdabletten	150 mg	Film - coated tablel	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	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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 0PF United Kingdom	Trimetazidine hydrochloride	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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Mylan dura GmbH Wittichstrasse 6 64295 Darmstadt Germany	Repaglinide	Repaglinid Mylan 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
Germany	Mylan dura GmbH Wittichstrasse 6 64295 Darmstadt Germany	Rizatriptan	Rizatriptan Mylan dura 10 mg Schmelztabletten	10 mg	Orodispersible tablet	Oral use
Germany	Panacea Biotech 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 Biotech Germany GmbH Landshuter Allee 8-10 D-80637 München Germany	Tacrolimus	Tacpan 1 mg Hartkapseln	1 mg	Capsule, hard	Oral use

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

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/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
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

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	5 mg	Film - coated tablet	Oral use
Greece	Abbott Laboratories Hellas ABEE Agiou Dimitriou 63 Alimos 17456 Greece	Escitalopram oxalate	Savandra	10 mg	Film - coated tablet	Oral use
Greece	Abbott Laboratories Hellas ABEE Agiou Dimitriou 63 Alimos 17456 Greece	Escitalopram oxalate	Savandra	15 mg	Film - coated tablet	Oral use
Greece	Abbott Laboratories Hellas ABEE Agiou Dimitriou 63 Alimos 17456 Greece	Escitalopram oxalate	Savandra	20 mg	Film - coated tablet	Oral use
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

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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Greece	Sieger Pharma A.E. Marathonos Avenue 106 Pikermi 19009 Greece	Desloratadine	Desloratadine/Sieger	5 mg	Film - coated tablet	Oral use
Greece	Sieger Pharma A.E. Marathonos Avenue 106 Pikermi 19009 Greece	Desloratadine	Desloratadine/Sieger	2,5 mg	Orodispersible tablet	Oral use
Greece	Sieger Pharma A.E. Marathonos Avenue 106 Pikermi 19009 Greece	Desloratadine	Desloratadine/Sieger	5 mg	Orodispersible tablet	Oral use
Hungary	Actavis Group PTC ehf. 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
Hungary	Alvogen IPCo S.ar.l. Rue Heienhaff 5 L-1736 Senningerberg Luxembourg	Desloratadine	Alvotadin 2.5 mg szájban diszpergálódó tableta	2,5 mg	Orodispersible 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 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
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

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

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 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
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

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 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
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

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 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

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 32 mg Tablets	32 mg	Tablet	Oral use
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Ireland	Niche Generics Limited 1 The Cam Centre Wilbury Way, Hitchin Hertfordshire SG4 0TW United Kingdom	Irbesartan	Irbesartan Niche 300mg film coated tablets	300 mg	Film - coated tablet	Oral use
Ireland	Wockhardt UK Limited Ash Road North Wrexham Industrial Estate Wrexham LL13 9UF United Kingdom	Clopidogrel hydrochloride	Clopidogrel 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

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	Film - coated tablet	Oral use
Italy	Doc Generici SRL Via Turati, 40 20121 Milano Italy	Desloratadine	DES LorATADINA DOC GENERICI	2,5 mg	Orodispersible tablet	Oral use
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

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

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	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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Latvia	Sandoz Pharmaceuticals d.d. Verovskova 57 Ljubljana SI-1000 Slovenia	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
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

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	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
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

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/hydroch lorothiazide	Irbesartanas/Hidrochlorotia zidas Torrent	300 mg/25 mg	Film - coated tablet	Oral use
Luxembourg	Mylan bvba/sprl Terhulpsesteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan Pharma 0,5 mg tabletten	0,5 mg	Tablet	Oral use
Luxembourg	Mylan bvba/sprl Terhulpsesteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan Pharma 1 mg tabletten	1 mg	Tablet	Oral use
Luxembourg	Mylan bvba/sprl Terhulpsesteenweg 6A 1560 Hoeilaart Belgium	Repaglinide	Repaglinide Mylan Pharma 2 mg tabletten	2 mg	Tablet	Oral use
Luxembourg	Mylan bvba/sprl Terhulpsesteenweg 6A 1560 Hoeilaart Belgium	Esomeprazole	Esomeprazole Mylan	20 mg	Gastro - resistant capsule, hard	Oral use
Luxembourg	Mylan bvba/sprl Terhulpsesteenweg 6A 1560 Hoeilaart Belgium	Esomeprazole	Esomeprazole 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
Malta	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Valsartan/hydrochl orthiazide	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 orthiazide	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 orthiazide	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
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

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 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

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	8 mg	tablet	Oral use
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

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	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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Abbott Laboratories Poland Sp. z o.o. ul. Postępu 21B 02-676 Warszawa Poland	Escitalopram	Savandra	15 mg	Film - coated tablet	Oral use
Poland	Abbott Laboratories Poland Sp. z o.o. ul. Postępu 21B 02-676 Warszawa Poland	Escitalopram	Savandra	20 mg	Film - coated tablet	Oral use
Poland	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Metformin	Metformin SR Actavis	500 mg	Film - coated tablet	Oral use
Poland	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Metformin	Metformin SR Actavis	750 mg	Film - coated tablet	Oral use
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
Poland	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice Poland	Desloratadine	Teslor fast	5 mg	Orodispersible tablet	Oral use
Poland	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice Poland	Desloratadine	Teslor fast junior	2,5 mg	Orodispersible tablet	Oral use

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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Irbesartan	Irbesartan Fair-Med	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
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

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	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 cilxetil	Kangen	8 mg	Tablet	Oral use
Poland	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Candesartan cilxetil	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

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

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	15 mg	Film - coated tablet	Oral use
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

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	25 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	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

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	200 mg	Film - coated tablet	Oral use
Portugal	Daquimed - Comércio de Produtos Farmacêuticos, S.A. Av. Associação Comercial e Industrial de Gondomar, 330 - Zona Industrial da Portelinha 4510-688 Fânzeres Portugal	Quetiapine	Quetiapina Daquimed	300 mg	Film - coated tablet	Oral use
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

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	100 mg/25 mg/200 mg	Film - coated tablet	Oral use
Portugal	Generis Farmacêutica, S. A. Rua João de Deus, 19 2700-487 Amadora Portugal	Levodopa/carbidopa/entacapone	Levodopa + Carbidopa + Entacapon Generis	125 mg/31,250 mg/200 mg	Film - coated tablet	Oral use
Portugal	Generis Farmacêutica, S. A. Rua João de Deus, 19 2700-487 Amadora Portugal	Levodopa/carbidopa/entacapone	Levodopa + Carbidopa + Entacapon Generis	150 mg/37,5 mg/200 mg	Film - coated tablet	Oral use
Portugal	Generis Farmacêutica, S. A. Rua João de Deus, 19 2700-487 Amadora Portugal	Levodopa/carbidopa/entacapone	Levodopa + Carbidopa + 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

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	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
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

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	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
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

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

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	150 mg	Capsule	Oral use
Portugal	Laboratórios Basi - Indústria Farmacêutica, S.A Parque Industrial Manuel Lourenço Ferreira, Lote 15 3450-232 Mortágua Portugal	Fluconazole	Fluconazol Basi	200 mg	Capsule	Oral use
Portugal	Labormed-Pharma, SA Theodor Pallady, 44B 032266 Bucharest Romania	Desloratadine	Desloratadina Labormed	5 mg	Orodispersible tablet	Oral use
Portugal	Labormed-Pharma, SA Theodor Pallady, 44B 032266 Bucharest Romania	Desloratadine	Desloratadina Labormed	2,5 mg	Orodispersible tablet	Oral use
Portugal	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 0PF United Kingdom	Cefpodoxime	Cefpodoxima Lupin	200 mg	Film - coated tablet	Oral use

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

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	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
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

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	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
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

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	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 - Miraflares 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

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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Romania	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	SAVANDRA 15 mg comprimate filmate	15 mg	Film - coated tablet	Oral use
Romania	Abbott Products SAS 42 rue Rouget de Lisle 92150 Suresnes France	Escitalopram	SAVANDRA 20 mg comprimate filmate	20 mg	Film - coated tablet	Oral use
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

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	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
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

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/ hydrochlorothiazide	Telmisartan HCT Dr. Reddy's 80 mg/12,5 mg comprimate	80 mg/12,5 mg	Tablet	Oral use
Romania	Dr. Reddy's Laboratories Romania SRL 71st-73rd Nicolae Caramfil, Floor 5, Space 10, Sector 1, Bucuresti, Romania	Telmisartan/ hydrochlorothiazide	Telmisartan HCT Dr. Reddy's 80 mg/25 mg comprimate	80 mg/25 mg	Tablet	Oral use
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Esomeprazole 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

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	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
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Candesartan cilixelil	Candesartan Mylan 4 mg comprimate	4 mg	Tablet	Oral use
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Candesartan cilixelil	Candesartan Mylan 8 mg comprimate	8 mg	Tablet	Oral use
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Candesartan cilixelil	Candesartan Mylan 16 mg comprimate	16 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	Rizatriptan benzoate	Rizatriptan Mylan 5 mg comprimate orodispersabile	5 mg	Orodispersible tablet	Oral use
Romania	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Rizatriptan benzoate	Rizatriptan Mylan 10 mg comprimate orodispersabile	10 mg	Orodispersible tablet	Oral use
Romania	Glenmark Pharmaceuticals s.r.o. Hvězdova 1716/2b 14078 Praha 4 Czech Republic	Trimetazidine	Apstar 35mg Comprimate cu eliberare prelungită	35 mg	Modified - release tablet	Oral use
Romania	Labormed Pharma SA Bd. Theodor Pallady nr. 44 B 032266, sector 3, București România	Desloratadine	Desloratadine Labormed 2.5 mg comprimate orodispersabile	2,5 mg	Orodispersible tablet	Oral use
Romania	Labormed Pharma SA Bd. Theodor Pallady nr. 44 B 032266, sector 3, București România	Desloratadine	Desloratadine Labormed 5 mg comprimate orodispersabile	5 mg	Orodispersible tablet	Oral use
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
Romania	Torrent Pharma SRL Str. Stirbei Voda nr. 36 et. 2, biroul A, sector 1 Bucharest Romania	Irbesartan	Irbesartan Torrent 75 mg comprimate filmate	75 mg	Film - coated tablet	Oral use
Romania	Torrent Pharma SRL Str. Stirbei Voda nr. 36 et. 2, biroul A, sector 1 Bucharest Romania	Irbesartan	Irbesartan Torrent 150 mg comprimate filmate	150 mg	Film - coated tablet	Oral use

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Romania	Torrent Pharma SRL Str. Stirbei Voda nr. 36 et. 2, biroul A, sector 1 Bucharest Romania	Irbesartan	Irbesartan Torrent 300 mg comprimate filmate	300 mg	Film - coated tablet	Oral use
Romania	Torrent Pharma SRL Str. Stirbei Voda nr. 36 et. 2, biroul A, sector 1 Bucharest Romania	Irbesartan/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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Slovak Republic	Alvogen IPCo S.à.r.l. 412F Route d'Esch L - 2086 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
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

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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Slovenia	Generics (UK) Ltd Station Close, Potters Bar Hertfordshire, EN6 1TL United Kingdom	Esomeprazole magnesium	Esomeprazol Mylan 40 mg trde gastrozistentne 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
Spain	Accord Healthcare, S.L.U. Moll de Barcelona s/n. World Trade Center. Edifici Est 6 ^a planta, 8039 Barcelona Spain	Metoclopramide	METOCLOPRAMIDA ACCORD 10 mg COMPRIMIDOS EFG	10 mg	Tablet	Oral use
Spain	Apotex Europe B.V. Darwinweg 20 NL 2333 CR Leiden Netherlands	Desloratadine	DES Loratadina APOTEX 5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA 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	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	Farmlider, 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	Farmlider, 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
Spain	Farmlider, S.A. Aragoneses 15 28108 Madrid Spain	Valsartan/hydrochl orothiazide	VALSARTAN/HIDROCLORO TIAZIDA CODRAMOL 320/12.5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	320 mg/12,5 mg	Film - coated tablet	Oral use
Spain	Farmlider, S.A. Aragoneses 15 28108 Madrid Spain	Valsartan/hydrochl orothiazide	VALSARTAN/HIDROCLORO TIAZIDA CODRAMOL 320/25 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	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
Spain	Farmlider, S.A. Aragoneses 15 28108 Madrid Spain	Valsartan/hydrochl orothiazide	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
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

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 20 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	20 mg	Film - coated tablet	Oral use
Spain	Laboratorios Combix, S.L.U. C/ Badajoz 2, Edificio 2 Pozuelo de Alarcon Madrid 28223 Spain	Escitalopram	ESCITALOPRAM COMBIX 5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	5 mg	Film - coated tablet	Oral use
Spain	Laboratorios Ranbaxy, S. L. U. Paseig de Gracia 9 7a Pl Barcelona 08007 Spain	Alendronic acid	ACIDO ALENDRONICO SEMANAL RANBAXY 70 mg COMPRIMIDOS EFG	70 mg	Tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L. Plom 2-4, 5º Planta 8038 Barcelona Spain	Donepezil	DONEPEZILO FLAS MYLAN PHARMACEUTICALS 10 mg COMPRIMIDOS 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

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	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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	PENSA PHARMA, S.A.U Jorge Comín (médico pediatra) 3 - bajos 46015– Valencia (Valencia) Spain	Alendronic acid	ACIDO ALENDRONICO 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	DESLOTATADINA 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	DESLOTATADINA 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	DESLOTATADINA TEVA 5 mg COMPRIMIDOS BUCODISPERSABLES EFG	5 mg	Orodispersible tablet	Oral use
Spain	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan	IRBESARTAN/HIDROCLOR OTIAZIDA WELDING 150 mg/12.5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	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
Spain	Welding GmbH & Co. KG Esplanade 39 D-20354 Hamburg Germany	Irbesartan	IRBESARTAN/HIDROCLOR OTIAZIDA 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/HIDROCLOR OTIAZIDA 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
Sweden	Bluefish Pharmaceuticals AB Torsgatan 11 SE-11123 Stockholm Sweden	Fluconazole	Fluconazol Bluefish	50 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	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

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	20 mg	Film - coated tablet	Oral use
Sweden	Mylan AB PO Box 230 33 SE-104 35 Stockholm Sweden	Eletriptan	Eletriptan Mylan	40 mg	Film - coated tablet	Oral use
Sweden	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	Valsartan Orion	40 mg	Film - coated tablet	Oral use
Sweden	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	Valsartan Orion	80 mg	Film - coated tablet	Oral use
Sweden	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
Sweden	Orion Corporation Orion Pharma PO BOX 65 02101 Espoo Finland	Valsartan	Valsartan Orion	320 mg	Film - coated tablet	Oral use
Sweden	Ranbaxy UK Ltd. Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE United Kingdom	Alendronic acid	Alendronat Ranbaxy Veckotablett 70 mg tabletter	70 mg	Tablet	Oral use
Sweden	Stada Arzneimittel AG Stadastrasse 2-18 DE-61118 Bad Vilbel Germany	Entacapone	Entakapon STADA	200 mg	Film - coated tablet	Oral use
The Netherlands	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirol Accord 5 mg, 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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirol Accord 0,5 mg filmomhulde tabletten	0,5 mg	Film - coated tablet	Oral use
The Netherlands	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirol Accord 1 mg 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

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	Metoclopramide hydrochloride	Metoclopramidemonohydro chloride Accord 10 mg, Tabletten	10 mg	Tablet	Oral use
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Brown & Burk UK, Ltd. 5, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Ebastine	Ebastine BB 10 mg orodispergeerbare tabletten	10 mg	Orodispersible tablet	Oral use
The Netherlands	Centrafarm B.V. Nieuwe Donk 3 4879 AC Etten Leur The Netherlands	Entacapone	Entacapone CF 200 mg, filmomhulde tablet	200 mg	Film - coated tablet	Oral use
The Netherlands	Fair-Med Healthcare GmbH Planckstrasse 13 DE-22765 Hamburg Germany	Ciprofloxacin	Ciprofloxacin Fair-Med 250 mg, filmomhulde tabletten	250 mg	Film - coated tablet	Oral use
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

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	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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
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
The Netherlands	Ranbaxy UK Ltd. Building 4, Chiswick Park 566 Chiswick High Road London, W4 5YE Untied 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

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

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

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/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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow HA1 4HF Middlesex United Kingdom	Ropinirole	Ropinirole 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
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

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	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
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

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	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
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

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	Clobazam	CLOBAZAM AUDEN 10mg TABLETS	10 mg	Tablet	Oral use
United Kingdom	Brown & Burk UK, Ltd. 5, Marryat 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, Marryat Close Hounslow TW4 5DQ Middlesex United Kingdom	Escitalopram oxalate	Escitalopram 5mg Film- coated tablets	5 mg	Film - coated tablet	Oral use
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

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 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
United Kingdom	Brown & Burk UK, Ltd. 5, Marryat 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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Dr Reddy's Laboratories (UK) Limited 6 Riverview Road, Beverley East Yorkshire HU17 0LD United Kingdom	Valsartan	Valsartan 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
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

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 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
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

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	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
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

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/ 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
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

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/hydroch lorothiazide	Irbesartan/Hydrochlorothia zide 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/hydroch lorothiazide	Irbesartan/Hydrochlorothia zide 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
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

Member State (in EEA)	Marketing Authorisation Holder	INN	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	FDC Pharma Unit 6, Fulcrum 1, Solent Way Whiteley, Fareham Hampshire PO15 7FE United Kingdom	Amlodipine	Amlodipine 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
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

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 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/carbidopa/ entacapone	Levodopa/Carbidopa/Entac apone film-coated tablets 150/37.5/200mg	150 mg/37,5 mg/200 mg	Film - coated tablet	Oral use
United Kingdom	Lupin (Europe) Limited Victoria Court, Bexton Road Knutsford, Cheshire WA16 0PF United Kingdom	Pantoprazole	Pantoprazole 20mg Gastro- Resistant tablets	20 mg	Gastro - resistant 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 0PF 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 0PA 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 0PA 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 0TW United Kingdom	irbesartan	Irbesartan Niche 150mg film-coated tablets	150 mg	Film - coated tablet	Oral use
United Kingdom	Niche Generics Limited 1 The Cam Centre Wilbury Way, Hitchin Hertfordshire SG4 0TW United Kingdom	irbesartan	Irbesartan Niche 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	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/hydroch lorothiazide	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/hydroch lorothiazide	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/hydroch lorothiazide	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
United Kingdom	Torrent Pharma GmbH Südwestpark 50 90449 Nürnberg 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	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