

**Summary of European Union decisions on marketing authorisations in respect of medicinal products
from 1 June 2014 to 30 June 2014**

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

(2014/C 243/02)

— Issuing, maintenance or modification of a national marketing authorisation

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorisation	Member State concerned	Date of notification
23.6.2014	Zolpidem	See Annex I	See Annex I	See Annex I	24.6.2014
30.6.2014	Crestor	See Annex II	See Annex II	See Annex II	1.7.2014

⁽¹⁾ OJ L 311, 28.11.01, p. 67.

⁽²⁾ OJ L 311, 28.11.01, p. 1.

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, route of administration, marketing authorisation holders in the Member States

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach, Austria	Zoldem 5 mg — Filmtabletten	5 mg	film-coated tablet	oral use
Austria	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach, Austria	Zoldem 10 mg — Filmtabletten	10 mg	film-coated tablet	oral use
Austria	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach, Austria	Zolpidem G.L. 10 mg — Filmtabletten	10 mg	film-coated tablet	oral use
Austria	Hexal Pharma GmbH, Stella-Klein-Löw-Weg 17, 1020 Wien, Austria	Zolpidem 'Hexal' — Filmtabletten	10 mg	film-coated tablet	oral use
Austria	Meda Pharma GmbH, Guggasse 15, 1110 Wien, Austria	Edluar 5 mg Sublingualtabletten	5 mg	sublingual tablet	sublingual use
Austria	Meda Pharma GmbH, Guggasse 15, 1110 Wien, Austria	Edluar 10 mg Sublingualtabletten	10 mg	sublingual tablet	sublingual use
Austria	ratiopharm Arzneimittel Vertriebs-GmbH, Albert-Schweitzer-Gasse 3, 1140 Wien, Austria	Zolpidem 'ratiopharm' 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Austria	sanofi-aventis GmbH, Saturn Tower, Leonard-Bernstein-Straße 10, 1220 Wien, Austria	Ivadal — Filmtabletten	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	STADA Arzneimittel GmbH, Muthgasse 36/ 2, 1190 Wien, Austria	Mondeal 10 mg — Filmtabletten	10 mg	film-coated tablet	oral use
Belgium	APOTEX NV Av. du Bourg. Etienne Demunter 5 box 8 1090 Jette Belgium	Zolpitop	10 mg	film-coated tablet	oral use
Belgium	APOTEX NV Av. du Bourg. Etienne Demunter 5 box 8 1090 Jette Belgium	Zolpitop	5 mg	film-coated tablet	oral use
Belgium	Eurogenerics S.A. Esplanade Heyssel, b22 1020 Bruxelles Belgium	Zolpidem EG	10 mg	film-coated tablet	oral use
Belgium	Eurogenerics S.A. Esplanade Heyssel, b22 1020 Bruxelles Belgium	Zolpidem EG	10 mg	effervescent tablet	oral use
Belgium	Ipca, Produtos Farmaceuticos, Unipessoal Lda Rua Chanceler-Mor 11 R/c Frt. Cacem 2735-615 Portugal	Zolpidem IPCA	5 mg	film-coated tablet	oral use
Belgium	Ipca, Produtos Farmaceuticos, Unipessoal Lda Rua Chanceler-Mor 11 R/c Frt. Cacem 2735-615 Portugal	Zolpidem IPCA	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Belgium	MEDA PHARMA Chaussee de la Hulpe 166 1170 Watermael-Boitsfort Belgium	Zolpeduar	5 mg	sublingual tablet	oral use
Belgium	MEDA PHARMA Chaussee de la Hulpe 166 1170 Watermael-Boitsfort Belgium	Zolpeduar	10 mg	sublingual tablet	oral use
Belgium	MYLAN BVBA/SPRL Terhulpsesteenweg 6A 1560 Hoeilaart Belgium	Zolpidem Mylan	10 mg	film-coated tablet	oral use
Belgium	SANDOZ N.V. Telecom Gardens Medialaan 40 1800 1800ilvoorde Belgium	Zolpidem Sandoz	10 mg	film-coated tablet	oral use
Belgium	SANOFI BELGIUM Airport Plaza, Montreal Building, Leonardo Da Vinciiaan 19 1831 Diegem Belgium	Stilnoct	10 mg	tablet	oral use
Belgium	SANOFI BELGIUM Airport Plaza, Montreal Building, Leonardo Da Vinciiaan 19 1831 Diegem Belgium	Zolpidem Sanofi-Aventis Belgium	10 mg	film-coated tablet	oral use
Belgium	TEVA PHARMA BELGIUM NV Laarstraat 16 2610 Wilrijk Belgium	Zolpidem Teva	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Belgium	TEVA PHARMA BELGIUM NV Laarstraat 16 2610 Wilrijk Belgium	Zolpidem Ratiopharm	10 mg	film-coated tablet	oral use
Bulgaria	ALKALOID-INT d.o.o. Šlandrova ulica 4 1231 Ljubljana-Črnuče Slovenia	Adorma	5 mg	film-coated tablet	oral use
Bulgaria	ALKALOID-INT d.o.o. Šlandrova ulica 4 1231 Ljubljana-Črnuče Slovenia	Adorma	10 mg	film-coated tablet	oral use
Bulgaria	Krka, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	Zolsana	5 mg	film-coated tablet	oral use
Bulgaria	Krka, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	Zolsana	10 mg	film-coated tablet	oral use
Bulgaria	Meda Pharma GmbH & Co. KG Benzstrasse 1 Bad Homburg v.d.H 61352 Germany	Edluar	5 mg	sublingual tablet	sublingual use
Bulgaria	Meda Pharma GmbH & Co. KG Benzstrasse 1 Bad Homburg v.d.H 61352 Germany	Edluar	10 mg	sublingual tablet	sublingual use
Bulgaria	Sanofi-Aventis Bulgaria EOOD, 103 Alexander Stamboliiski Blvd. Building Sofia Tower Sofia 1303 Bulgaria	Stilnox	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Croatia	Alkaloid d.o.o., Ulica grada Vukovara 226 F, Zagreb, Croatia	Lunata 5 mg filmom obložene tablete	5 mg	film-coated tablet	oral use
Croatia	Alkaloid d.o.o., Ulica grada Vukovara 226 F, Zagreb, Croatia	Lunata 10 mg filmom obložene tablete	10 mg	film-coated tablet	oral use
Croatia	Krka — farma d.o.o., Radnička cesta 48, Zagreb, Croatia	Zolsana 5 mg filmom obložene tablete	5 mg	film-coated tablet	oral use
Croatia	Krka — farma d.o.o., Radnička cesta 48, Zagreb, Croatia	Zolsana 10 mg filmom obložene tablete	10 mg	film-coated tablet	oral use
Croatia	Pliva Hrvatska d.o.o., Prilaz baruna Filipovića 25, Zagreb, Croatia	Zonadin 5 mg tablete	5 mg	film-coated tablet	oral use
Croatia	Pliva Hrvatska d.o.o., Prilaz baruna Filipovića 25, Zagreb, Croatia	Zonadin 10 mg tablete	10 mg	film-coated tablet	oral use
Croatia	Sandoz d.o.o., Maksimirska 120, Zagreb, 1000, Croatia	Sanval 5 mg filmom obložene tablete	5 mg	film-coated tablet	oral use
Croatia	Sandoz d.o.o., Maksimirska 120, Zagreb, 1000, Croatia	Sanval 10 mg filmom obložene tablete	10 mg	film-coated tablet	oral use
Cyprus	Sanofi-Aventis Cyprus Ltd Charalambou Mouskou 14 Lefkosia 2015 Cyprus	Stilnox	10 mg	film-coated tablet	oral use
Czech Republic	ALKALOID-INT d.o.o. Šlandrova ulica 4 1231 Ljubljana-Črnuče Slovenia	ADORMA 5 MG	5 mg	film-coated tablet	oral use
Czech Republic	ALKALOID-INT d.o.o. Šlandrova ulica 4 1231 Ljubljana-Črnuče Slovenia	ADORMA 10 MG	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Czech Republic	Apotex Europe B.V. Darwinweg 20 NL 2333 CR Leiden Netherlands	APO-ZOLPIDEM 10 MG	10 mg	film-coated tablet	oral use
Czech Republic	Generics [UK] Ltd. Station Close EN6 1TL Hertfordshire — Potters Bar United Kingdom	ZOLPIDEM MYLAN	10 mg	film-coated tablet	oral use
Czech Republic	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia	ZOLSANA 10 MG	10 mg	film-coated tablet	oral use
Czech Republic	MEDA Pharma s.r.o. Kodaňská 1441/46 110 00 Prague 10 Czech Republic	EDLUAR 5 MG SUBLING- VÁLNÍ TABLETY	5 mg	sublingual tablet	sublingual use
Czech Republic	MEDA Pharma s.r.o. Kodaňská 1441/46 110 00 Prague 10 Czech Republic	EDLUAR 10 MG SUBLING- VÁLNÍ TABLETY	10 mg	sublingual tablet	sublingual use
Czech Republic	Orion Corporation Orionintie 1/A FI-02200 Espoo Finland	ZOLPIDEM ORION 10 MG	10 mg	film-coated tablet	oral use
Czech Republic	ratiofarm GmbH Graf Arco Strasse 3 D-89079 Ulm Germany	ZOLPIDEM-RATIOPHARM 10 MG	10 mg	film-coated tablet	oral use
Czech Republic	SANDOZ s.r.o. U nákladového nádraží 3265/10 130 00 Prague 3 Czech Republic	SANVAL 10 MG	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Czech Republic	sanofti-aventis, s.r.o. Evropská 846/176a 160 00 Prague 6 — Vokovice Czech Republic	STILNOX	10 mg	film-coated tablet	oral use
Czech Republic	SVUS Pharma a.s., Smetanovo nábřeží 1238/20a 500 02 Hradec Králové Czech Republic	ZOLPINOX	10 mg	film-coated tablet	oral use
Czech Republic	Takeda GmbH Byk-Gulden-Str. 2 78467 Konstanz Germany	HYPNOGEN	10 mg	film-coated tablet	oral use
Czech Republic	Vitalbans Oy Varastokatu 8 13500 Hämeenlinna Finland	ZOLPIDEM VITABALANS 10 MG POTAHOVANÉ TA- BLETY	10 mg	film-coated tablet	oral use
Denmark	Actavis Group PTC ehf. Reykjavíkurvegur 76-78 IS-220 Hafnarfjörður Iceland	Zolpidem 'Actavis'	10 mg	film-coated tablet	oral use
Denmark	Actavis Group PTC ehf. Reykjavíkurvegur 76-78 IS-220 Hafnarfjörður Iceland	Zolpidem 'Actavis'	5 mg	film-coated tablet	oral use
Denmark	Generics [UK] Ltd. Station Close EN6 1TL Hertfordshire — Potters Bar United Kingdom	Zolpidem 'Generics'	10 mg	film-coated tablet	oral use
Denmark	HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark	Zolpidem 'Hexal'	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Denmark	Meda AS, Solvang 8, DK-3450 Allerød, Denmark	Edluar	5 mg	sublingual tablet	sublingual use
Denmark	Meda AS, Solvang 8, DK-3450 Allerød, Denmark	Edluar	10 mg	sublingual tablet	sublingual use
Denmark	PharmaCoDane ApS, Marielundvej 46 A, DK-2730 Herlev, Denmark	Zonoct	10 mg	film-coated tablet	oral use
Denmark	sanoﬁ-aventis Denmark A/S, Slotsmarken 13, DK-2970 Hørsholm, Denmark	Stilnoct	10 mg	film-coated tablet	oral use
Denmark	Synthon BV, Microweg 22, NL-6545 CM Nijmegen, The Netherlands	Zolpidem 'Genthon'	5 mg	film-coated tablet	oral use
Denmark	Synthon BV, Microweg 22, NL-6545 CM Nijmegen, The Netherlands	Zolpidem 'Genthon'	10 mg	film-coated tablet	oral use
Denmark	Vitalbans Oy Varastokatu 8 13500 Hämeenlinna Finland	Zolpidem 'Vitalbans'	10 mg	film-coated tablet	oral use
Estonia	Krka, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	ZOLSANA	5 mg	tablet	oral use
Estonia	Krka, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	ZOLSANA	10 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Estonia	Meda Pharma GmbH & Co. KG Benzstrasse 1 Bad Homburg v.d.H 61352 Germany	EDLUAR	5 mg	sublingual tablet	oral use
Estonia	Meda Pharma GmbH & Co. KG Benzstrasse 1 Bad Homburg v.d.H 61352 Germany	EDLUAR	10 mg	sublingual tablet	oral use
Estonia	Sandoz d.d. Verovškova 57, 1000 Ljubljana, Slovenia	ZOLPIDEM SANDOZ 10 MG	10 mg	tablet	oral use
Estonia	Sanofi-Aventis Estonia OÜ Pärnu mnt 139E/2 11317 Tallinn Estonia	STILNOX	10 mg	tablet	oral use
Estonia	Takeda GmbH 2 Byk-Gulden Strasse 78467 Konstanz Germany	HYPNOGEN	10 mg	tablet	oral use
Estonia	Vitalbans Oy Varastokatu 8 13500 Hämeenlinna Finland	ZOLPIDEM VITABALANS 10 MG	10 mg	tablet	oral use
Finland	Actavis Group PTC ehf. Reykjavíkurvegur 76-78 IS-220 Hafnarfjörður Iceland	Stella	5 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Finland	Actavis Group PTC ehf. Reykjavíkurvegur 76-78 IS-220 Hafnarfjörður Iceland	Stella	10 mg	film-coated tablet	oral use
Finland	Hexal A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Zolpidem Hexal	10 mg	film-coated tablet	oral use
Finland	Meda Oy Vaisalandie 4 02130 Espoo Finland	Edluar	5 mg	sublingual tablet	sublingual use
Finland	Meda Oy Vaisalandie 4 02130 Espoo Finland	Edluar	10 mg	sublingual tablet	sublingual use
Finland	Orion Corporation Orionintie 1/A FI-02200 Espoo Finland	Somnor	10 mg	film-coated tablet	oral use
Finland	ratiopharm GmbH Graf Arco Strasse 3 D-89079 Ulm Germany	Zolpidem-Ratiopharm	10 mg	film-coated tablet	oral use
Finland	Sanofi Oy Huopalahdentie 24 P.O.Box 22 00350 Helsinki Finland	Stilnoct	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Finland	Vitalbans Oy Varastokatu 8 13500 Hämeenlinna Finland	Zolpidem Vitalbans	10 mg	film-coated tablet	oral use
France	LABORATOIRES ALTER 3, avenue de la Baltique ZI de Courtaboeuf 91140 Villebon Sur Yvette France	ZOLPIDEM ALTER	10 mg	film-coated tablet	oral use
France	Actavis Group PTC ehf. Reykjavíkurvegur 76-78 IS-220 Hafnarfjörður Iceland	ZOLPIDEM ACTAVIS	10 MG	film-coated tablet	oral use
France	ARROW GENERIQUES 26, avenue Tony Garnier 69007 Lyon France	ZOLPIDEM ARROW	10 mg	film-coated tablet	oral use
France	BIOGARAN 15, boulevard Charles de Gaulle 92700 Colombes FRANCE	ZOLPIDEM ALMUS	10 mg	film-coated tablet	oral use
France	BIOGARAN 15, boulevard Charles de Gaulle 92700 Colombes FRANCE	ZOLPIDEM BIOGARAN	10 mg	film-coated tablet	oral use
France	CRISTERS 22 quai Gallieni 92150 Suresnes France	ZOLPIDEM CRISTERS	10 mg	film-coated tablet	oral use
France	CTRS Route de la Ganne 36170 Saint Benoit du Sault France	ZOLPIDEM CTRS	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	EG LABO — LABORATOIRES EUROGE- NERICS 'Le Quintet' — bâtiment A 12, rue Danjou 92517 Boulogne Billancourt Cedex France	ZOLPIDEM EG	10 mg	film-coated tablet	oral use
France	EG LABO — LABORATOIRES EUROGE- NERICS 'Le Quintet' — bâtiment A 12, rue Danjou 92517 Boulogne Billancourt Cedex France	ZOLPIDEM EG	10 mg	coated tablet	oral use
France	Genfarma B.V. Postbus 2062 1500 GB Zaandam The Netherlands	ZOLPIDEM RATIOPHARM	10 mg	coated tablet	oral use
France	Kiron Pharmaceutica BV Groesbeekseweg 11 Nijmegen, 6524 CK The Netherlands	ZOLPIDEM KIRION	5 mg	film-coated tablet	oral use
France	MEDA PHARMA 25, boulevard de l'Amiral Bruix 75016 Paris FRANCE	EDLUAR	5 mg	sublingual tablet	oral use
France	MEDA PHARMA 25, boulevard de l'Amiral Bruix 75016 Paris FRANCE	EDLUAR	10 mg	sublingual tablet	oral use
France	MYLAN SAS 117, allée des Parcs 69800 Saint-Priest France	ZOLPIDEM MYLAN	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	PHARMACHEMIE BV Swensweg 5 — Haarlem PO Box 552 2003 RN Haarlem PAYS-BAS The Netherlands	ZOLPIDEM TEVA	10 mg	coated tablet	oral use
France	RANBAXY PHARMACIE GENERIQUES 11-15 Quai Dion Bouton 92800 Puteaux FRANCE	ZOLPIDEM RPG	10 mg	film-coated tablet	oral use
France	RATIOPHARM GMBH Graf Arco Strasse 3 89079 Ulm ALLEMAGNE	ZOLPIDEM RATIOPHARM	10 mg	film-coated tablet	oral use
France	SANDOZ 49, avenue Georges Pompidou 92300 Levallois-Perret France	ZOLPIDEM GNR	10 mg	film-coated tablet	oral use
France	SANDOZ 49, avenue Georges Pompidou 92300 Levallois-Perret France	ZOLPIDEM GENERES	10 mg	film-coated tablet	oral use
France	SANDOZ 49, avenue Georges Pompidou 92300 Levallois-Perret France	ZOLPIDEM SANDOZ	10 mg	film-coated tablet	oral use
France	SANOFI AVENTIS FRANCE 1-13, boulevard Romain Rolland 75014 Paris France	STILNOX	10 mg	film-coated tablet	oral use
France	SANOFI AVENTIS FRANCE 1-13, boulevard Romain Rolland 75014 Paris France	ZOLPIDEM ZENTIVA	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	Synthon BV, Microweg 22, NL-6545 CM Nijmegen, The Netherlands	ZOLPIDEM BAYER	10 mg	film-coated tablet	oral use
France	Synthon BV, Microweg 22, NL-6545 CM Nijmegen, The Netherlands	ZOLPIDEM BAYER	5 mg	film-coated tablet	oral use
France	TEVA SANTE 110, Esplanade du Général de Gaulle 92931 Paris La Défense Cedex FRANCE	ZOLPIDEM TEVA	10 mg	film-coated tablet	oral use
France	ZYDUS FRANCE 25, rue des Peupliers ZAC Les Hautes Pâtures — Parc d'Activités des Peupliers 92000 Nanterre FRANCE	ZOLPIDEM ZYDUS	10 mg	film-coated tablet	oral use
Germany	1 A Pharma Keltentring 1 + 3 82041 Oberhaching Germany	Zolpidem 10 — 1A-Pharma	10 mg	film-coated tablet	oral use
Germany	AbZ-Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Zolpidem AbZ 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Germany	Actavis Deutschland GmbH & Co. KG Willy-Brandt-Allee 2 81829 München Germany	Zolpidem-Actavis 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Germany	Aliud Pharma GmbH Gottlieb-Daimler-Str. 19 89150 Laichingen Germany	Zolpidem AL 10 mg Film- tabletten	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Aliud Pharma GmbH Gottlieb-Daimler-Str. 19 89150 Laichingen Germany	Zolpidem AL 5 mg Filmtabletten	5 mg	film-coated tablet	oral use
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Zolpidem Aristo 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Germany	AbZ-Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Zolpidem-CT 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Germany	AbZ-Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Zolpidem-CT 5 mg Filmtabletten	5 mg	film-coated tablet	oral use
Germany	Dolorgiet GmbH & Co. KG Otto-von-Guericke-Str. 1 53757 Sankt Augustin Germany	Zolpidem real 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 90449 Nürnberg Germany	Zolpidem Heumann 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 90449 Nürnberg Germany	Zolpidem Heumann 5 mg Filmtabletten	5 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Hexal Aktiengesellschaft Industriestr. 25 83607 Holzkirchen Germany	Zolpidem Hexal 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Germany	IPCA — Produtos Farmacêuticos Unipessoal, Lda. Rua José Nogueira Vaz, Lote 104 — Lj Esq 2625-099 Povoia de Santa Iria Portugal	Zolpidem IPCA 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Germany	IPCA — Produtos Farmacêuticos Unipessoal, Lda. Rua José Nogueira Vaz, Lote 104 — Lj Esq 2625-099 Povoia de Santa Iria Portugal	Zolpidem IPCA 5 mg Film- tabletten	5 mg	film-coated tablet	oral use
Germany	Juta Pharma GmbH Gutenbergstr. 13 24941 Flensburg Germany	Zolpi-Q 10 mg Filmtable- tten	10 mg	film-coated tablet	oral use
Germany	Krewel Meuselbach GmbH Krewelstr. 2 53783 Eitorf Germany	Zolpinox 10 mg	10 mg	film-coated tablet	oral use
Germany	Meda Pharma GmbH & Co. KG Benzstrasse 1 Bad Homburg v.d.H 61352 Germany	Edluar 10 mg Sublingualta- bletten	10 mg	sublingual tablet	oral use
Germany	Meda Pharma GmbH & Co. KG Benzstrasse 1 Bad Homburg v.d.H 61352 Germany	Edluar 5 mg Sublingualta- bletten	5 mg	sublingual tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Mylan dura GmbH Wittichstr. 6 64295 Darmstadt Germany	Zolpidem dura 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Germany	neuraxpharm Arzneimittel GmbH Elisabeth-Selbert-Str. 23 40764 Langenfeld Germany	Zolpidem-neuraxpharm 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Germany	neuraxpharm Arzneimittel GmbH Elisabeth-Selbert-Str. 23 40764 Langenfeld Germany	Zolpidem-neuraxpharm 5 mg Filmtabletten	5 mg	film-coated tablet	oral use
Germany	ratiofarm GmbH Graf Arco Strasse 3 D-89079 Ulm Germany	Zolpidem-ratiofarm 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Germany	ratiofarm GmbH Graf Arco Strasse 3 D-89079 Ulm Germany	Zolpidem-ratiofarm 5 mg Filmtabletten	5 mg	film-coated tablet	oral use
Germany	Sandoz Pharmaceuticals GmbH Raiffeisenstr. 11 83607 Holzkirchen Germany	Zolpidem Sandoz 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Germany	Sanofi-Aventis Deutschland GmbH Industriepark Höchst, Gebäude K703 65926 Frankfurt am Main Germany	Bikalim	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Sanofi-Aventis Deutschland GmbH Industriepark Höchst, Gebäude K703 65926 Frankfurt am Main Germany	Stilnox	10 mg	film-coated tablet	oral use
Germany	Stadapharm GmbH Stadastr. 2-18 61118 Bad Vilbel Germany	Zolpidem STADA 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Germany	Stadapharm GmbH Stadastr. 2-18 61118 Bad Vilbel Germany	Zolpidem STADA 5 mg Filmtabletten	5 mg	film-coated tablet	oral use
Germany	TAD Pharma GmbH Heinz-Lohmann-Str. 5 27472 Cuxhaven Germany	Zolpidem TAD 10 mg	10 mg	film-coated tablet	oral use
Germany	Vitalans Oy Varastokatu 8 13500 Hämeenlinna Finland	Zolpidem Vitalans 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Germany	Winthrop Arzneimittel GmbH Brünigstr. 50 65926 Frankfurt am Main Germany	Zolpi-Lich 10 mg Filmtabletten	10 mg	film-coated tablet	oral use
Greece	IOULIA AND IRENE TSETI PHARMACEUTICAL LABORATORIES ABEE, INTERMED ABEE, Kalyftaki 27, Kifissia 14564 Greece	HYPNONORM	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Greece	ITF HELLAS S.A. Areos 103 and Ag. Triados 36, Palaio Faliro 17562 Greece	ONIRIA	10 mg/ml	oral drops, solution	oral use
Greece	ITF PHARMA KERESKEDELMI ES SZOL- GALTATO KFT, BUDAPEST, HUNGAR H-1056, Budapest Duna u.1 Hungary	KALINICTA	10 mg/ml	oral drops, solution	oral use
Greece	SANOFL-AVENTIS AEBE 348 SYNGROU AVENUE, BUILDING A, KALLITHEA 17674 Greece	STILNOX	10 mg	film-coated tablet	oral use
Hungary	EGIS Gyógyszergyár Nyrt. Keresztúri út 30- 38. Budapest 1106 Hungary	PIDEZOL 10 mg filmtabletta	10 mg	film-coated tablet	oral use
Hungary	ExtractumPharma zRt. Megyeri út 64. Budapest 1044 Hungary	ZOLEP 10 mg filmtabletta	10 mg	film-coated tablet	oral use
Hungary	Generics (UK) Ltd. Albany Gate, Darkes Lane, Potters bar Herts EN61AG United Kingdom	SOMNOGEN 10 mg filmta- bletta	10 mg	film-coated tablet	oral use
Hungary	ITF Pharma Kft Duna u. 1. Budapest 1056 Hungary	ONIRIA 10 mg/ml belső- leges oldatos cseppek	10 mg/ml	oral drops, solution	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Hungary	Krka d.d. Novo Mesto Smarjeska cesta 6. Novo Mesto 8501 Slovenia	ZOLSANA 5 mg filmtablet- tta	5 mg	film-coated tablet	oral use
Hungary	Krka d.d. Novo Mesto Smarjeska cesta 6. Novo Mesto 8501 Slovenia	ZOLSANA 10 mg filmta- bletta	10 mg	film-coated tablet	oral use
Hungary	LEK Pharmaceuticals d.d. Verovskova 57 Ljubljana Slovenia	SANVAL 5 mg filmtabletta	5 mg	film-coated tablet	oral use
Hungary	LEK Pharmaceuticals d.d. Verovskova 57 Ljubljana Slovenia	SANVAL 10 mg filmtabletta	10 mg	film-coated tablet	oral use
Hungary	Meda Pharma Hungary Kft Váci út 91. Budapest 1139 Hungary	EDLUAR 5 mg nyelvvalatti tabletta	5 mg	sublingual tablet	sublingual use
Hungary	Meda Pharma Hungary Kft Váci út 91. Budapest 1139 Hungary	EDLUAR 10 mg nyelvvalatti tabletta	10 mg	sublingual tablet	sublingual use
Hungary	Sanofi-Aventis Magyarország Zrt Tó u. 1-5 Budapest 1045 Hungary	STILNOX 10 mg filmtabletta	10 mg	film-coated tablet	oral use
Hungary	Teva Magyarország Zrt Repülőtéri út 5. Gödöllő 2100 Hungary	ZOLPIDEM-RATIOPHARM 10 mg filmtabletta	10 mg	film-coated tablet	oral use
Hungary	Vitalbans Oy Varastokatu 8. Hämeenlinna 13500 Finland	ZOLPIDEM VITABALANS 10 mg filmtabletta	10 mg	film-coated tablet	oral use
Hungary	Vulm CZ a.s. Olivova 1888 Ricany 25101 Czech Republic	INSOM 10 mg pezsgőtable- tta	10 mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Hungary	Zentiva k.s. Dolný Mecholupy, U kabelovny 130 Prague 10, 10237 Czech Republic	HYPNOGEN 10 mg filmtabletta	10 mg	film-coated tablet	oral use
Iceland	LYFIS ehf., Grensásvegur 22, 108 Reykjavík, Iceland	Zolpidem LYFIS	10 mg	film-coated tablet	oral use
Iceland	Meda AB, Pipers väg 2A, Box 906, SE-170 09, Sweden	Edluar	5 mg	sublingual tablet	oral use
Iceland	Meda AB, Pipers väg 2A, Box 906, SE-170 09, Sweden	Edluar	10 mg	sublingual tablet	oral use
Iceland	Mylan AB, Ynglingagatan 14, 10435 Stockholm, Sweden.	Zolpidem Mylan	10 mg	film-coated tablet	oral use
Iceland	Sanofi Aventis Norge Strandveien 15, 1366 Lysaker, Norway	Stilnoct	5 mg	film-coated tablet	oral use
Iceland	Sanofi Aventis Norge Strandveien 15, 1366 Lysaker, Norway	Stilnoct	10 mg	film-coated tablet	oral use
Ireland	Clonmel Healthcare Ltd Waterford Road Clonmel Co. Tipperary Ireland	Nytamel 5 mg Film-coated Tablets	5 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Clonmel Healthcare Ltd Waterford Road Clonmel Co. Tipperary Ireland	Nytamel 10 mg Film-coated Tablets.	10 mg	film-coated tablet	oral use
Ireland	McDermott Laboratories Ltd t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland	Zoldem 10 mg film-coated tablets	10 mg	film-coated tablet	oral use
Ireland	Meda Health Sales Ireland Limited Unit 34/35 Block A Dunboyne Business Park Dunboyne Co Meath Ireland	Edluar 5 mg sublingual tablets	5 mg	sublingual tablet	oral use
Ireland	Meda Health Sales Ireland Limited Unit 34/35 Block A Dunboyne Business Park Dunboyne Co Meath Ireland	Edluar 10 mg sublingual tablets	10 mg	sublingual tablet	oral use
Ireland	Rowex Ltd, Bantry, Co. Cork, Ireland	Zolnod 10 mg film-coated tablets	10 mg	film-coated tablet	oral use
Ireland	Sanofi-Aventis Ireland Limited T/A Sanofi, Citywest Business Campus, Dublin 24, Ireland	Stilnoct 5 mg Film-coated Tablets	5 mg	film-coated tablet	oral use
Ireland	Sanofi-Aventis Ireland Limited T/A Sanofi, Citywest Business Campus, Dublin 24, Ireland	Stilnoct 10 mg Film-coated Tablets	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Teva Pharma B. V. Computerweg 10 3542 DR Utrecht The Netherlands	Zolpidem Tartrate Teva 5 mg Film-coated Tablets	5 mg	film-coated tablet	oral use
Ireland	Teva Pharma B. V. Computerweg 10 3542 DR Utrecht The Netherlands	Zolpidem Tartrate Teva 10 mg Film-coated Tablets	10 mg	film-coated tablet	oral use
Italy	Actavis Group PTC ehf. Reykjavíkurvegur 76-78 IS-220 Hafnarfjörður Iceland	ZOLPIDEM ACTAVIS	10 mg	film-coated tablet	oral use
Italy	Doc Generici S.r.l. Turati 40, Milano — 20121 Italy	ZOLPIDEM DOC GENERICI	5 mg	film-coated tablet	oral use
Italy	Doc Generici S.r.l. Turati 40, Milano — 20121 Italy	ZOLPIDEM DOC GENERICI	10 mg	film-coated tablet	oral use
Italy	EG S.p.a. Via Scarlatti, 31, Milano — 20124 Italy	ZOLPIDEM EG	10 mg	film-coated tablet	oral use
Italy	FIDIA Farmaceutici S.p.a. Via Ponte della Fabbrica, 3/a, Abano Terme, Padova — 35031 Italy	OPSYCON	10 mg	film-coated tablet	oral use
Italy	HEXAL S.p.a. Largo Umberto Boccioni 1 21040 Origgio Varese Italy	ZOLPIDEM HEXAL	10 mg	film-coated tablet	oral use
Italy	IPCA — Produtos Farmacêuticos Unipessoal, Lda. Rua José Nogueira Vaz, Lote 104 — Lj Esq 2625-099 Povoas de Santa Iria Portugal	ZOLPIDEM IPCA	5 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	IPCA — Produtos Farmacêuticos Unipessoal, Lda. Rua José Nogueira Vaz, Lote 104 — Lj Esq 2625-099 Povoia de Santa Iria Portugal	ZOLPIDEM IPCA	10 mg	film-coated tablet	oral use
Italy	ITALFARMACO S.p.A. Viale Fulvio Testi 330, 20126 Milano, Italy	SONIREM	10 mg/ml	oral drops, solution	oral use
Italy	LIFEPHARMA S.P.A. Via dei Lavoratori 54, 20092 Cinisello Balsamo, Milano — Italy	ZOLPREM	10 mg/ml	oral drops, solution	oral use
Italy	MEDA PHARMA S.P.A., Viale brenta 18, 20139 Milano — Italy	ZOLPEDUAR	5 mg	sublingual tablet	oral use
Italy	MEDA PHARMA S.P.A., Viale brenta 18, 20139 Milano — Italy	ZOLPEDUAR	10 mg	sublingual tablet	oral use
Italy	Ratiopharm GmbH Graf Arco Strasse 3 D-89079 Ulm Germany	ZOLPIDEM RATIOPHARM	10 mg	film-coated tablet	oral use
Italy	Sandoz S.p.a. Largo Umberto Boccioni, 1, Origgio, Varese — 21040 Italy	ZOLPIDEM SANDOZ	10 mg	film-coated tablet	oral use
Italy	Sanofi-aventis SpA, Viale Bodio 37/b, 20158 Milano Italy	STILNOX	10 mg	film-coated tablet	oral use
Italy	Sanofi-aventis SpA, Viale Bodio 37/b, 20158 Milano Italy	NOTTEM	10 mg	film-coated tablet	oral use
Italy	Teva Italia S.r.l. — via Messina 38 — 20154 Milano Italy	ZOLPIDEM TEVA	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	ZENTIVA ITALIA S.R.L. — Viale Bodio 37/ b, 20158 Milano Italy	ZOLPIDEM ZENTIVA	10 mg	film-coated tablet	oral use
Latvia	Krka, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	Zolsana 5 mg coated tablets	5 mg	coated tablet	oral use
Latvia	Krka, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	Zolsana 10 mg coated ta- blets	10 mg	coated tablet	oral use
Latvia	Meda Pharma GmbH & Co. KG Benzstrasse 1 Bad Homburg v.d.H 61352 Germany	Edluar 5 mg sublingual ta- blets	5 mg	sublingual tablet	sublingual use
Latvia	Meda Pharma GmbH & Co. KG Benzstrasse 1 Bad Homburg v.d.H 61352 Germany	Edluar 10 mg sublingual tablets	10 mg	sublingual tablet	sublingual use
Latvia	Sandoz d.d. Verovškova 57, 1000 Ljubljana, Slovenia	Zolpidem Sandoz 10 mg film-coated tablets	10 mg	film-coated tablet	oral use
Latvia	sanofi-aventis Latvia SIA, Kr.Valdemara 33- 8 Rīga, LV 1010, Latvia	Stilnox 10 mg film-coated tablets	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Latvia	Vitalbans Oy Varastokatu 8 13500 Hämeenlinna Finland	Zolpidem Vitalbans 10 mg film-coated tablets	10 mg	film-coated tablet	oral use
Latvia	Zentiva, k.s. U kabelovny 130 Prague 10, Dolni Mecholupy 10237 Czech Republic	Hypnogen 10 mg film- coated tablets	10 mg	film-coated tablet	oral use
Lithuania	Krka, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	Zolsana	10 mg	film-coated tablet	oral use
Lithuania	Krka, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	Zolsana	5 mg	film-coated tablet	oral use
Lithuania	Sandoz d.d. Verovškova 57, 1000 Ljubljana, Slovenia	Zolpidem Sandoz	10 mg	film-coated tablet	oral use
Lithuania	UAB 'SANOFI-AVENTIS LIETUVA' A. Juozapavičiaus 6/2 g. LT-09310 Vilnius Lithuania	Stilnox	10 mg	film-coated tablet	oral use
Lithuania	Vitalbans Oy Varastokatu 8 13500 Hämeenlinna Finland	Zolpidem Vitalbans	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Lithuania	Zentiva, k.s. U kabelovny 130 Prague 10, Dolni Mecholupy 10237 Czech Republic	HYPNOGEN	10 mg	film-coated tablet	oral use
Luxembourg	MYLAN BVBA/SPRL Terhulpssteenweg 6A 1560 Hoeilaart Belgium	Dodorest	10 mg	coated tablet	oral use
Luxembourg	SANOFI BELGIUM Airport Plaza, Montreal Building, Leonardo Da Vinci laan 19 1831 Diegem Belgium	Stilnoct	10 mg	coated tablet	oral use
Luxembourg	Eurogenerics S.A. Esplanade Heyssel, b22 1020 Bruxelles Belgium	Zolpidem EG cpr.eff.	10 mg	effervescent tablet	oral use
Luxembourg	Eurogenerics S.A. Esplanade Heyssel, b22 1020 Bruxelles Belgium	Zolpidem EG cpr.pellic.	10 mg	coated tablet	oral use
Luxembourg	Genthon BV Microweg, 22 6545 Nijmegen The Netherlands	Zolpidem Genthion	10 mg	coated tablet	oral use
Luxembourg	Genthon BV Microweg, 22 6545 Nijmegen The Netherlands	Zolpidem Genthion	5 mg	coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Apotex Europe B.V. Darwinweg 20 NL 2333 CR Leiden The Netherlands	Zolpitop	10 mg	coated tablet	oral use
Luxembourg	Apotex Europe B.V. Darwinweg 20 NL 2333 CR Leiden The Netherlands	Zolpitop	5 mg	coated tablet	oral use
Luxembourg	MEDA PHARMA Chaussee de la Hulpe 166 1170 Watermael-Boitsfort Belgium	Zolpeduar	10 mg	sublingual tablet	sublingual use
Luxembourg	MEDA PHARMA Chaussee de la Hulpe 166 1170 Watermael-Boitsfort Belgium	Zolpeduar	5 mg	sublingual tablet	sublingual use
Malta	Sanofi Malta Ltd. St. Julian's Rd. San Gwann SGN 2805 Malta	Stilnox	10 mg	film-coated tablet	oral use
Malta	Pharma MT 103, Stuart Street, Gzira, Malta	Nytamel	10 mg	film-coated tablet	oral use
Norway	Sanofi Aventis Norge Strandveien 15, 1366 Lysaker, Norway	Stilnoct	5 mg	film-coated tablet	oral use
Norway	Sanofi Aventis Norge Strandveien 15, 1366 Lysaker, Norway	Stilnoct	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Norway	Actavis Norway AS, P.O.BOX 409, 0213 Skoyen, OSLO, Norway	Zolpidem Actavis	5 mg	film-coated tablet	oral use
Norway	Actavis Norway AS, P.O.BOX 409, 0213 Skoyen, OSLO, Norway	Zolpidem Actavis	10 mg	film-coated tablet	oral use
Norway	Meda Norge, P.O.BOX 194, 1371 ASKER, Norway	Edluar	5 mg	sublingual tablet	oral use
Norway	Meda Norge, P.O.BOX 194, 1371 ASKER, Norway	Edluar	10 mg	sublingual tablet	oral use
Norway	Vitalbans Oy Varastokatu 8 13500 Hämeenlinna Finland	Zolpidem Vitalbans	10 mg	film-coated tablet	oral use
Poland	Actavis Group PTC ehf. Reykjavíkurvegur 76-78 IS-220 Hafnarfjörður Iceland	Noxizol	10 mg	film-coated tablet	oral use
Poland	Apotex Europe B.V. Darwinweg 20 NL 2333 CR Leiden The Netherlands	Apo-Zolpin	10 mg	film-coated tablet	oral use
Poland	Farma-Projekt Sp. z o.o. ul. Józefińska 2 30-529 Kraków Poland	Xentic	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Poland	Generics [UK] Ltd. Station Close EN6 1TL Hertfordshire — Potters Bar United Kingdom	ZolpiGen	10 mg	film-coated tablet	oral use
Poland	Ipca, Produtos Farmaceuticos, Unipessoal Lda Rua Chanceler-Mor 11 R/c Frt. Cacem 2735-615 Portugal	Zolpidem IPCA	5 mg	film-coated tablet	oral use
Poland	Ipca, Produtos Farmaceuticos, Unipessoal Lda Rua Chanceler-Mor 11 R/c Frt. Cacem 2735-615 Portugal	Zolpidem IPCA	10 mg	film-coated tablet	oral use
Poland	Italfarmaco S.p.A. Viale Fulvio 330 20126 Milano Italy	Sonirem	10 mg/ml	oral drops, solution	oral use
Poland	Krka, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	Zolsana	10 mg	film-coated tablet	oral use
Poland	Meda Pharma GmbH & Co. KG Benzstrasse 1 Bad Homburg v.d.H 61352 Germany	Edluar	5 mg	sublingual tablet	oral use
Poland	Meda Pharma GmbH & Co. KG Benzstrasse 1 Bad Homburg v.d.H 61352 Germany	Edluar	10 mg	sublingual tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Poland	Orion Corporation Orionintie 1/A FI-02200 Espoo Finland	Onirex	10 mg	film-coated tablet	oral use
Poland	Pabianickie Zakłady Farmaceutyczne Polfa S.A. ul. Marszałka J. Piłsudskiego 5 95-200 Pabianice Poland	Polsen	10 mg	film-coated tablet	oral use
Poland	Pfizer Europe MA EEIG Ramsgate Road Kent, Sandwich CT13 9 NJ United Kingdom	Zolpidem Pfizer	10 mg	film-coated tablet	oral use
Poland	Polfarmex S.A. Józefów 9 99-300 Kutno Poland	Nasen	10 mg	film-coated tablet	oral use
Poland	Sandoz GmbH ul. Biochemiestrasse 10 Kundli 6250 Austria	Sanval	10 mg	film-coated tablet	oral use
Poland	Sanofi-Aventis France 1-13 boulevard Romain Rolland 75014 Paris France	Stilnox	10 mg	film-coated tablet	oral use
Poland	Vitalbans Oy Varastokatu 8 13500 Hämeenlinna Finland	Zolpidem Vitalbans	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Poland	VULM CZ, a.s. Olivova 1888 Ricany 251 01 Czech Republic	Insom	10 mg	effervescent tablet	oral use
Poland	Zakłady Farmaceutyczne POLPHARMA S. A. Pelplińska 19 83-200 Starogard Gdański Poland	Zolpic	10 mg	film-coated tablet	oral use
Poland	Zentiva, k.s. U kabelovny 130 Prague 10, Dolni Mecholupy 10237 Czech Republic	Hypnogen	10 mg	film-coated tablet	oral use
Portugal	Actavis A/S Sucursal Rua Virgílio Correia, 11 — A 1600-219 Lisboa Portugal	Zolpidem Actavis	10 mg	film-coated tablet	oral use
Portugal	Aurobindo Pharma (Portugal), Unipessoal Lda. Av. do Forte, n° 3 — Parque Suécia, Edifício. IV, 2° 2794-038 Carnaxide Portugal	Zolpidem Aurobindo	5 mg	film-coated tablet	oral use
Portugal	Aurobindo Pharma (Portugal), Unipessoal Lda. Av. do Forte, n° 3 — Parque Suécia, Edifício. IV, 2° 2794-038 Carnaxide Portugal	Zolpidem Aurobindo	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Cinfa Portugal, Lda. Av. Tomás Ribeiro, 43 — Bloco 2, 3º F — Edifício Neopark 2790-221 Carnaxide Portugal	Zolpidem Cinfa 10 mg Comprimidos	10 mg	film-coated tablet	oral use
Portugal	Generis Farmacéutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Zolpidem Generis 5 mg Comprimidos Revestidos	5 mg	film-coated tablet	oral use
Portugal	Generis Farmacéutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Zolpidem Generis 10 mg Comprimidos Revestidos	10 mg	film-coated tablet	oral use
Portugal	Genthon GmbH Groesbecker Weg, 1 D-47559 Kranenburg Germany	Zolpidem 5 mg Comprimi- dos Revestidos	5 mg	film-coated tablet	oral use
Portugal	IPCA — Produtos Farmacêuticos Unipes- soal, Lda. Rua José Nogueira Vaz, Lote 104 — Lj Esq 2625-099 Povoia de Santa Iria Portugal	Zolpidem IPCA	5 mg	film-coated tablet	oral use
Portugal	IPCA — Produtos Farmacêuticos Unipes- soal, Lda. Rua José Nogueira Vaz, Lote 104 — Lj Esq 2625-099 Povoia de Santa Iria Portugal	Zolpidem IPCA	10 mg	film-coated tablet	oral use
Portugal	Labesfal Genéricos, S.A Avenida Dr. Afonso Costa, 1370 3465-051 Campo de Besteiros Portugal	Zolpidem Labesfal	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product 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	Cymerion	10 mg	film-coated tablet	oral use
Portugal	Meda Pharma — Produtos Farmacêuticos, S.A. Rua do Centro Cultural, 13 1749-066 Lisboa Portugal	Edluar	5 mg	sublingual tablet	sublingual use
Portugal	Meda Pharma — Produtos Farmacêuticos, S.A. Rua do Centro Cultural, 13 1749-066 Lisboa Portugal	Edluar	10 mg	sublingual tablet	sublingual 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	Zolpidem Mylan	10 mg	film-coated tablet	oral use
Portugal	Ratiopharm — Comércio e Indústria de Produtos Farmacêuticos, Lda. Lagoas Park, Edifício 5 A, Piso 2 2740-245 Porto Salvo Portugal	Zolpidem Ratiopharm 10 mg Comprimidos Revestidos	10 mg	film-coated tablet	oral use
Portugal	Sandoz Farmacêutica, Lda. Alameda da Beloura, Edifício 1, 2º — Escritório 15 2710-693 Sintra Portugal	Zolpidem Sandoz	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Sanofi — Produtos Farmacéuticos, Lda. Empreendimento Lagoas Park Edifício 7, 3. ^o Piso 2740-244 Porto Salvo Portugal	Stilnox	10 mg	film-coated tablet	oral use
Portugal	Wynn Industrial Pharma, S.A. Rua Tierno Galvan, Torre 3, 16. ^o Piso, Amoreiras 1070-274 Lisboa Portugal	Zolpidem Wynn	10 mg	film-coated tablet	oral use
Romania	ALKALOID-INT d.o.o. Šlandrova ulica 4 1231 Ljubljana-Črnuče Slovenia	ZADOBRA 5 mg	5 mg	film-coated tablet	oral use
Romania	ALKALOID-INT d.o.o. Šlandrova ulica 4 1231 Ljubljana-Črnuče Slovenia	ZADOBRA 10 mg	10 mg	film-coated tablet	oral use
Romania	ITALFARMACO S.p.A. Viale Fulvio Testi 330, 20126 Milano, Italia	ONIRIA 10 mg/ml	10 mg/ml	oral drops, solution	oral use
Romania	Krka, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	ZOLSANA 5 mg	5 mg	film-coated tablet	oral use
Romania	Krka, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	ZOLSANA 10 mg	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Romania	LABORMED PHARMA S.A. B-dul Theodor Pallady nr. 44B Sector 3, Bucureşti, România	ZOLPIDEM 10 mg	10 mg	film-coated tablet	oral use
Romania	LEK farmacevtska družba d.d. Verovškova 57 1526 Ljubljana Slovenia	SANVAL 10 mg	10 mg	film-coated tablet	oral use
Romania	Meda Pharma GmbH & Co. KG Benzstrasse 1 Bad Homburg v.d.H 61352 Germany	EDLUAR 5 mg	5 mg	sublingual tablet	oral use
Romania	Meda Pharma GmbH & Co. KG Benzstrasse 1 Bad Homburg v.d.H 61352 Germany	EDLUAR 10 mg	10 mg	sublingual tablet	oral use
Romania	S.C. ANTIBIOTICE S.A., Str. Valea Lupului nr.1, Iaşi, România	ZOLPIDEM ATB 10 mg	10 mg	film-coated tablet	oral use
Romania	SANOFL-AVENTIS ROMÂNIA S.R.L. Str. Izvor, Nr. 80, Et. 6-11 Sector 5, Bucureşti, România	STILNOX 10 mg	10 mg	film-coated tablet	oral use
Slovak Republic	ALKALOID-INT d.o.o. Šlandrova ulica 4 1231 Ljubljana-Črnuče Slovenia	ADORMA 5 mg filmom obalené tablety	5 mg	film-coated tablet	oral use
Slovak Republic	ALKALOID-INT d.o.o. Šlandrova ulica 4 1231 Ljubljana-Črnuče Slovenia	ADORMA 10 mg filmom obalené tablety	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	Generics [UK] Ltd. Station Close EN6 1TL Hertfordshire — Potters Bar United Kingdom	Zolpidem Mylan 10 mg	10 mg	film-coated tablet	oral use
Slovak Republic	Orion Corporation Orionintie 1/A FI-02200 Espoo Finland	Zolpidem Orion 10 mg	10 mg	film-coated tablet	oral use
Slovak Republic	Sandoz d.d. Verovškova 57, 1000 Ljubljana, Slovenia	SANVAL 5 mg	5 mg	film-coated tablet	oral use
Slovak Republic	Sandoz d.d. Verovškova 57, 1000 Ljubljana, Slovenia	SANVAL 10 mg	10 mg	film-coated tablet	oral use
Slovak Republic	sanofi-aventis Slovakia s.r.o. Einsteinova 24 85101 Bratislava Slovak Republic	STILNOX	10 mg	film-coated tablet	oral use
Slovak Republic	SVUS Pharma a.s., Smetanovo nábřeží 1238/20a 500 02 Hradec Králové Czech Republic	ZOLPINOX	10 mg	film-coated tablet	oral use
Slovak Republic	Takeda GmbH 2 Byk-Gulden Strasse 78467 Konstanz Germany	HYPNOGEN	10 mg	film-coated tablet	oral use
Slovak Republic	Vitalbans Oy Varastokatu 8 13500 Hämeenlinna Finland	Zolpidem Vitalbans 10 mg filmom obalené tablety	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Slovenia	ALKALOID-INT d.o.o. Šlandrova ulica 4 1231 Ljubljana-Črnuče Slovenia	Perluna 10 mg filmsko obožene tablete	10 mg	film-coated tablet	oral use
Slovenia	ALKALOID-INT d.o.o. Šlandrova ulica 4 1231 Ljubljana-Črnuče Slovenia	Perluna 5 mg filmsko obožene tablete	5 mg	film-coated tablet	oral use
Slovenia	Krka, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	Zolsana 10 mg filmsko obožene tablete	10 mg	film-coated tablet	oral use
Slovenia	Krka, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	Zolsana 5 mg filmsko obožene tablete	5 mg	film-coated tablet	oral use
Slovenia	LEK farmacevtska družba d.d. Verovškova 57 1526 Ljubljana Slovenia	Sanval 10 mg filmsko obožene tablete	10 mg	film-coated tablet	oral use
Slovenia	LEK farmacevtska družba d.d. Verovškova 57 1526 Ljubljana Slovenia	Sanval 5 mg filmsko obožene tablete	5 mg	film-coated tablet	oral use
Slovenia	Meda Pharma GmbH & Co. KG Benzstrasse 1 Bad Homburg v.d.H 61352 Germany	Edluar 10 mg podjezične tablete	10 mg	sublingual tablet	sublingual use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Slovenia	Meda Pharma GmbH & Co. KG Benzstrasse 1 Bad Homburg v.d.H 61352 Germany	Edluar 5 mg podjezične tablete	5 mg	sublingual tablet	sublingual use
Slovenia	Vitalbans Oy Varastokatu 8 13500 Hämeenlinna Finland	Zolpidem Vitalbans 10 mg filmsko obložene tablete	10 mg	film-coated tablet	oral use
Spain	ANGELINI FARMACEUTICA, S.A. Osi, 7-9 Barcelona. 08034. SPAIN	DALPARAN 10 mg COM- PRIMIDOS RECUBIERTOS CON PELICULA	10 mg	film-coated tablet	oral use
Spain	Apotex Europe B.V. Darwinweg 20 NL 2333 CR Leiden The Netherlands	ZOLPIDEM APOTEX 10 mg COMPRIMIDOS RECUBIER- TOS CON PELICULA EFG	10 mg	film-coated tablet	oral use
Spain	BEXAL FARMACEUTICA, S.A Centro Em- presarial Osa Mayor. Avda. Osa Mayor, 4 — Area B, Aravaca (Madrid). 28023. SPAIN	ZOLPIDEM BEXALABS 10 mg COMPRIMIDOS CON CUBIERTOS CON PE- LICULA EFG	10 mg	film-coated tablet	oral use
Spain	BEXAL FARMACEUTICA, S.A Centro Em- presarial Osa Mayor. Avda. Osa Mayor, 4 — Area B, Aravaca (Madrid). 28023. SPAIN	ZOLPIDEM BEXAL 10 mg COMPRIMIDOS RECUBIER- TOS EFG	10 mg	film-coated tablet	oral use
Spain	FARMALIDER, S.A. Aragoneses, 2, Alco- bendas (Madrid). 28108. SPAIN	ZOLPIDEM FARMALIDER 10 mg COMPRIMIDOS RE- CUBIERTOS EFG	10 mg	film-coated tablet	oral use
Spain	GENERFARMA, S.L. Ronda Isaac Peral, 6 Parque Tecnológico 46980 Paterna (Valen- cia) SPAIN	ZOLPIDEM DESGEN 5 mg COMPRIMIDOS EFG	5 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Spain	GENERFARMA, S.L. Ronda Isaac Peral, 6 Parque Tecnológico 46980 Paterna (Valencia) SPAIN	ZOLPIDEM DESGEN 10 mg COMPRIMIDOS EFG	10 mg	tablet	oral use
Spain	GERMED FARMACEUTICA S.L. Chile, 8 — 2ª planta. Oficina 203, Las Matas (Madrid). 28290. SPAIN	ZOLPIDEM EDIGEN 10 mg COMPRIMIDOS RECUBIERTOS EFG	10 mg	film-coated tablet	oral use
Spain	LABORATORIO STADA, S.L. Frederic Mompou, 5, Sant Just Desvern (Barcelona). 08960 SPAIN	ZOLPIDEM STADA 10 mg COMPRIMIDOS RECUBIERTOS EFG	10 mg	film-coated tablet	oral use
Spain	LABORATORIOS CINFA, S.A. Olaz-Chipi, 10. Poligono Industrial Areta .Huarte-Pamplona (Navarra) 31620 SPAIN	ZOLPIDEM CINFA 10 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	10 mg	film-coated tablet	oral use
Spain	LABORATORIOS NORMON, S.A. Ronda de Valdecarrizo, 6, Tres Cantos (Madrid). 28760. SPAIN	ZOLPIDEM NORMON 10 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	10 mg	film-coated tablet	oral use
Spain	MEDA PHARMA S.A.U Avda. de Castilla, 2. Edif. Berlin. 2ª planta. Parque Empresarial San Fernando, San Fernando de Henares (Madrid).28830. SPAIN	EDLUAR 10 MG COMPRIMIDOS SUBLINGUALES	10 mg	sublingual tablet	oral use
Spain	MEDA PHARMA S.A.U Avda. de Castilla, 2. Edif. Berlin. 2ª planta. Parque Empresarial San Fernando, San Fernando de Henares (Madrid).28830. SPAIN	EDLUAR 5 MG COMPRIMIDOS SUBLINGUALES	5 mg	sublingual tablet	oral use
Spain	MYLAN PHARMACEUTICALS, S.L. Plom 2- 4, 5ª Planta, Barcelona. 08038. SPAIN	ZOLPIDEM MYLAN 10 mg COMPRIMIDOS RECUBIERTOS EFG	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Spain	PHARMAGENUS, S.A. Avda. Camí Real, 51-57 Palau-solita i Plegamans (Barcelona). 08184. SPAIN	ZOLPIDEM PHARMAGENUS 5 mg COMPRIMIDOS	5 mg	tablet	oral use
Spain	PHARMAGENUS, S.A. Avda. Camí Real, 51-57 Palau-solita i Plegamans (Barcelona). 08184. SPAIN	ZOLPIDEM PHARMAGENUS 10 mg COMPRIMIDOS EFG	10 mg	tablet	oral use
Spain	RATIOPHARM ESPAÑA, S.A. C/Anabel Segura 11, Edificio Albatros B 1ª Planta, Alcobendas, Madrid. 28108. SPAIN	ZOLPIDEM RATIOPHARM 10 mg COMPRIMIDOS RECUBIERTOS EFG	10 mg	film-coated tablet	oral use
Spain	RATIOPHARM ESPAÑA, S.A. C/Anabel Segura 11, Edificio Albatros B 1ª Planta, Alcobendas, Madrid. 28108. SPAIN	ZOLPIDEM TEVAGEN 10 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	10 mg	film-coated tablet	oral use
Spain	RATIOPHARM ESPAÑA, S.A. C/Anabel Segura 11, Edificio Albatros B 1ª Planta, Alcobendas, Madrid. 28108. SPAIN	ZOLPIDEM TEVAGEN 5 mg COMPRIMIDOS RECUBIERTOS CON PELICULA	5 mg	film-coated tablet	oral use
Spain	SANDOZ FARMACÉUTICA, S.A. Avda. Osa Mayor, 4 28023 Aravaca (Madrid) Spain	ZOLPIDEM SANDOZ 10 mg COMPRIMIDOS EFG	10 mg	tablet	oral use
Spain	SANOFI AVENTIS, S.A. Josep Plá, 2, Barcelona. 08019 SPAIN	STILNOX 10 mg COMPRIMIDOS RECUBIERTOS CON PELICULA	10 mg	film-coated tablet	oral use
Spain	TEVA GENERICOS ESPAÑOLA S.L.U. C/Anabel Segura, 11 Edificio Albatros B, 1 planta Alcobendas (Madrid). 28108. SPAIN	ZOLPIDEM TEVA 10 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Spain	Zentiva, k.s. U kabelovny 130 Prague 10, Dolni Mecholupy 10237 Czech Republic	ZOLPIDEM ZENTIVA 10 mg COMPRIMIDOS RE- CUBIERTOS CON PELICU- LA EFG	10 mg	film-coated tablet	oral use
Sweden	Actavis Group PTC ehf. Reykjavíkurvegur 76-78 IS-220 Hafnarfjörður Iceland	Zolpidem Actavis	5 mg	film-coated tablet	oral use
Sweden	Actavis Group PTC ehf. Reykjavíkurvegur 76-78 IS-220 Hafnarfjörður Iceland	Zolpidem Actavis	10 mg	film-coated tablet	oral use
Sweden	Hexal A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Zolpidem HEXAL	10 mg	film-coated tablet	oral use
Sweden	Ranbaxy (UK) Ltd, Building 4 Chiswick Park London W4 5YE United Kingdom	Zolpidem Ranbaxy	5 mg	film-coated tablet	oral use
Sweden	Ranbaxy (UK) Ltd, Building 4 Chiswick Park London W4 5YE United Kingdom	Zolpidem Ranbaxy	10 mg	film-coated tablet	oral use
Sweden	Meda AB, Pipers väg 2A, Box 906, SE-170 09, Sweden	Edluar	5 mg	sublingual tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Sweden	Meda AB, Pipers väg 2A, Box 906, SE-170 09, Sweden	Edluar	10 mg	sublingual tablet	oral use
Sweden	Mylan AB Box 23033 104 35 Stockholm Sweden	Zolpidem Mylan	10 mg	film-coated tablet	oral use
Sweden	Orifarm Generics A/S Energivej 15 POB 69 DK-5260 Odense S Denmark	Zolpidem Orifarm	5 mg	film-coated tablet	oral use
Sweden	Orifarm Generics A/S Energivej 15 POB 69 DK-5260 Odense S Denmark	Zolpidem Orifarm	10 mg	film-coated tablet	oral use
Sweden	ratiopharm GmbH Graf Arco Strasse 3 D-89079 Ulm Germany	Zolpidem ratiopharm	5 mg	film-coated tablet	oral use
Sweden	ratiopharm GmbH Graf Arco Strasse 3 D-89079 Ulm Germany	Zolpidem ratiopharm	10 mg	film-coated tablet	oral use
Sweden	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Zolpidem Sandoz	5 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Sweden	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Zolpidem Sandoz	10 mg	film-coated tablet	oral use
Sweden	sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Stilnoct	5 mg	film-coated tablet	oral use
Sweden	sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Stilnoct	10 mg	film-coated tablet	oral use
Sweden	STADA Arzneimittel AG Stadastrasse 2-18 DE-61118 Bad Vilbel Germany	Zolpidem STADA	5 mg	film-coated tablet	oral use
Sweden	STADA Arzneimittel AG Stadastrasse 2-18 DE-61118 Bad Vilbel Germany	Zolpidem STADA	10 mg	film-coated tablet	oral use
Sweden	Synthon BV, Microweg 22, NL-6545 CM Nijmegen, The Netherlands	Zolpidem Genthon	5 mg	film-coated tablet	oral use
Sweden	Synthon BV, Microweg 22, NL-6545 CM Nijmegen, The Netherlands	Zolpidem Genthon	10 mg	film-coated tablet	oral use
Sweden	Vitalbans Oy Varastokatu 8 13500 Hämeenlinna Finland	Zolpidem Vitalbans	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Actavis B.V. Baarnsche Dijk 1 3741 LN BAARN The Netherlands	Zolpidemtartraat Actavis 5 mg, tabletten	5 mg	tablet	oral use
The Netherlands	Actavis B.V. Baarnsche Dijk 1 3741 LN BAARN The Netherlands	Zolpidemtartraat Actavis 10 mg, tabletten	10 mg	tablet	oral use
The Netherlands	ADOH B.V. Godfried Bomansstraat 31 6543 JA NIJMEGEN The Netherlands	Zolpidemtartraat ADOH bruistabletten 10 mg, bruistabletten	10 mg	effervescent tablet	oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA HAARLEM The Netherlands	Zolpidemtartraat 5 mg PCH, filmomhulde tabletten	5 mg	film-coated tablet	oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA HAARLEM The Netherlands	Zolpidemtartraat 10 mg PCH, filmomhulde tabletten	10 mg	film-coated tablet	oral use
The Netherlands	ratiopharm Nederland B.V. Swensweg 5 2031 GA HAARLEM The Netherlands	Zolpidemtartraat ratio- pharm 5 mg, tabletten	5 mg	tablet	oral use
The Netherlands	ratiopharm Nederland B.V. Swensweg 5 2031 GA HAARLEM The Netherlands	Zolpidemtartraat ratio- pharm 10 mg, tabletten	10 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
The Netherlands	ratiopharm Nederland B.V. Swensweg 5 2031 GA HAARLEM The Netherlands	Zolpidemtartraat ratio- pharm 5 mg, filmomhulde tabletten	5 mg	film-coated tablet	oral use
The Netherlands	ratiopharm Nederland B.V. Swensweg 5 2031 GA HAARLEM The Netherlands	Zolpidemtartraat ratio- pharm 10 mg, filmomhulde tabletten	10 mg	film-coated tablet	oral use
The Netherlands	ratiopharm Nederland B.V. Swensweg 5 2031 GA HAARLEM The Netherlands	Zolpidemtartraat ratio- pharm 10 mg, filmomhulde tabletten	10 mg	film-coated tablet	oral use
The Netherlands	Sandoz B.V. Veluwezoom 22 1327 AH ALMERE The Netherlands	Zolpidemtartraat Sandoz 10 mg, filmomhulde table- tten	10 mg	film-coated tablet	oral use
The Netherlands	Sandoz B.V. Veluwezoom 22 1327 AH ALMERE The Netherlands	Zolpidemtartraat Sandoz 5, filmomhulde tabletten 5 mg	5 mg	film-coated tablet	oral use
The Netherlands	Sandoz B.V. Veluwezoom 22 1327 AH ALMERE The Netherlands	Zolpidemtartraat Sandoz 10, filmomhulde tabletten 10 mg	10 mg	film-coated tablet	oral use
The Netherlands	Synthon B.V. Microweg 22 6545 CM NIJMEGEN The Netherlands	Zolpidemtartraat 5 mg, fil- momhulde tabletten	5 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Synthon B.V. Microweg 22 6545 CM NIJMEGEN The Netherlands	Zolpidemtartraat 10 mg, filmomhulde tabletten	10 mg	film-coated tablet	oral use
The Netherlands	Synthon B.V. Microweg 22 6545 CM NIJMEGEN The Netherlands	Zolpidemtartraat 5 mg, fil- momhulde tabletten	5 mg	film-coated tablet	oral use
The Netherlands	Synthon B.V. Microweg 22 6545 CM NIJMEGEN The Netherlands	Zolpidemtartraat 10 mg, filmomhulde tabletten	10 mg	film-coated tablet	oral use
The Netherlands	Synthon B.V. Microweg 22 6545 CM NIJMEGEN The Netherlands	Zolpidemtartraat 5 mg, fil- momhulde tabletten	5 mg	film-coated tablet	oral use
The Netherlands	Synthon B.V. Microweg 22 6545 CM NIJMEGEN The Netherlands	Zolpidemtartraat 10 mg, filmomhulde tabletten	10 mg	film-coated tablet	oral use
The Netherlands	ADOH B.V. Godfried Bomansstraat 31 6543 JA NIJMEGEN The Netherlands	Zolpidemtartraat ADOH 10 mg, bruistabletten	10 mg	effervescent tablet	oral use
The Netherlands	Apotex Europe B.V. Darwinweg 20 NL 2333 CR Leiden The Netherlands	Zolpidemtartraat Apotex 5 mg, filmomhulde tabletten	5 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Apotex Europe B.V. Darwinweg 20 NL 2333 CR Leiden The Netherlands	Zolpidemtartraat Apotex 10 mg, filmomhulde table- tten	10 mg	film-coated tablet	oral use
The Netherlands	Centrafarm B.V. Nieuwe Donk 3 4879 AC ETTEN LEUR The Netherlands	Zolpidemtartraat CF 5 mg, film-omhulde tabletten	5 mg	film-coated tablet	oral use
The Netherlands	Centrafarm B.V. Nieuwe Donk 3 4879 AC ETTEN LEUR The Netherlands	Zolpidemtartraat CF 10 mg, film-omhulde tabletten	10 mg	film-coated tablet	oral use
The Netherlands	Eurogenerics S.A. Esplanade Heyssel, b22 1020 Bruxelles Belgium	Zolpidem Eurogenerics bruis 10 mg bruistabletten, bruistabletten	10 mg	effervescent tablet	oral use
The Netherlands	FIDIA Farmaceutici S.p.a. Via Ponte della Fabbrica, 3/a, Abano Terme, Padova — 35031 Italy	Zolpidemtartraat 10 mg, filmomhulde tabletten	10 mg	film-coated tablet	oral use
The Netherlands	Genthon BV Microweg, 22 6545 Nijmegen The Netherlands	Zolpidemtartraat 5 mg, fil- momhulde tabletten	5 mg	film-coated tablet	oral use
The Netherlands	Genthon BV Microweg, 22 6545 Nijmegen The Netherlands	Zolpidemtartraat 10 mg, filmomhulde tabletten	10 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Meda Pharma B.V. Krijgsman 20 1186 DM AMSTELVEEN The Netherlands	Edluar 5 mg, tablet voor sublinguaal gebruik	5 mg	sublingual tablet	sublingual use
The Netherlands	Meda Pharma B.V. Krijgsman 20 1186 DM AMSTELVEEN The Netherlands	Edluar 10 mg, tablet voor sublinguaal gebruik	10 mg	sublingual tablet	sublingual use
The Netherlands	Mylan B.V. Dieselweg 25 3752 LB BUNSCHOTEN The Netherlands	Zolpidemtartraat Mylan 10 mg, filmomhulde table- tten	10 mg	film-coated tablet	oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA HAARLEM The Netherlands	Zolpidemtartraat 5 PCH, filmomhulde tabletten 5 mg	5 mg	film-coated tablet	oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA HAARLEM The Netherlands	Zolpidemtartraat 10 PCH, filmomhulde tabletten 10 mg	10 mg	film-coated tablet	oral use
The Netherlands	Sanofi-Aventis Netherlands B.V. Kampenringweg 45 D-E 2803 PE GOUDA The Netherlands	Stilnoct, tabletten 10 mg	10 mg	tablet	oral use
The Netherlands	STADA Arzneimittel AG Stadastrasse 2-18 DE-61118 Bad Vilbel Germany	Zolpidemtartraat Stada 5 mg, filmomhulde tabletten	5 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
The Netherlands	STADA Arzneimittel AG Stadastrasse 2-18 DE-61118 Bad Vilbel Germany	Zolpidemtartraat Stada 10 mg, filmomhulde tabletten	10 mg	film-coated tablet	oral use
The Netherlands	Synthon B.V. Microweg 22 6545 CM NIJMEGEN The Netherlands	Zolpidemtartraat 10 mg, filmomhulde tabletten	10 mg	film-coated tablet	oral use
United Kingdom	Actavis UK Limited, Whiddon Valley, Barnstaple, North Devon EX32 8NS United Kingdom	Zolpidem Tartrate 5 mg tablets	5 mg	film-coated tablet	oral use
United Kingdom	Actavis UK Limited, Whiddon Valley, Barnstaple, North Devon EX32 8NS United Kingdom	Zolpidem Tartrate 10 mg tablets	10 mg	film-coated tablet	oral use
United Kingdom	ALKALOID-INT d.o.o. Šlandrova ulica 4 1231 Ljubljana-Črnuče Slovenia	Zolpidem Tartrate 5 mg film-coated tablets	5 mg	film-coated tablet	oral use
United Kingdom	ALKALOID-INT d.o.o. Šlandrova ulica 4 1231 Ljubljana-Črnuče Slovenia	Zolpidem Tartrate 10 mg film-coated tablets	10 mg	film-coated tablet	oral use
United Kingdom	Aventis Pharma Limited, One Onslow Street, Guildford, Surrey GU1 4SY United Kingdom	Stilnoct 5 mg film-coated tablets	5 mg	coated tablet	oral use
United Kingdom	Aventis Pharma Limited, One Onslow Street, Guildford, Surrey GU1 4SY United Kingdom	Stilnoct 10 mg film-coated tablets	10 mg	coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Bristol Laboratories Limited, Unit 3, Canal-side, Northbridge Road, Berkhamsted, Hertfordshire HP4 1EG United Kingdom	Zolpidem Tartrate 5 mg film-coated tablets	5 mg	film-coated tablet	oral use
United Kingdom	Bristol Laboratories Limited, Unit 3, Canal-side, Northbridge Road, Berkhamsted, Hertfordshire HP4 1EG United Kingdom	Zolpidem Tartrate 10 mg film-coated tablets	10 mg	film-coated tablet	oral use
United Kingdom	Generics [UK] Ltd. Station Close EN6 1TL Hertfordshire — Potters Bar United Kingdom	Zolpidem 10 mg film-coated tablets	10 mg	film-coated tablet	oral use
United Kingdom	Meda Pharmaceuticals Limited, Skyway House, Parsonage Road, Takeley, Bishops Stortford CM22 6PU United Kingdom	Edluar 5 mg sublingual tablets	5 mg	sublingual tablet	oral use
United Kingdom	Meda Pharmaceuticals Limited, Skyway House, Parsonage Road, Takeley, Bishops Stortford CM22 6PU United Kingdom	Edluar 10 mg sublingual tablets	10 mg	sublingual tablet	oral use
United Kingdom	Amneal Pharma Europe Limited, 70 Sir John Rogerson's Quay, Dublin 2, Ireland	Zolpidem Tartrate 5 mg film-coated tablets	5 mg	film-coated tablet	oral use
United Kingdom	Amneal Pharma Europe Limited, 70 Sir John Rogerson's Quay, Dublin 2, Ireland	Zolpidem Tartrate 10 mg film-coated tablets	10 mg	film-coated tablet	oral use
United Kingdom	ratiopharm GmbH Graf Arco Strasse 3 D-89079 Ulm Germany	Zolpidem Tartrate 5 mg film-coated tablets	5 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	ratiopharm GmbH Graf Arco Strasse 3 D-89079 Ulm Germany	Zolpidem Tartrate 10 mg film-coated tablets	10 mg	film-coated tablet	oral use
United Kingdom	Sandoz Limited, Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR United Kingdom	Zolpidem Tartrate 10 mg tablets	10 mg	film-coated tablet	oral use
United Kingdom	Teva UK Limited, Brampton Road, Hamp- den Park, Eastbourne, East Sussex BN22 9AG United Kingdom	Zolpidem Tartrate 5 mg, film-coated tablets	5 mg	film-coated tablet	oral use
United Kingdom	Teva UK Limited, Brampton Road, Hamp- den Park, Eastbourne, East Sussex BN22 9AG United Kingdom	Zolpidem Tartrate 10 mg, film-coated tablets	10 mg	film-coated tablet	oral use
United Kingdom	Tillomed Laboratories Limited, 3 Howard Road, Eaton Socon, St Neots, Cambridge- shire PE19 8ET United Kingdom	Zolpidem 10 mg film- coated tablets	10 mg	film-coated tablet	oral use
United Kingdom	Winthrop Pharmaceuticals UK Limited, One Onslow Street, Guildford, Surrey GU1 4YS United Kingdom	Zolpidem Tartrate 5 mg ta- blets	5 mg	film-coated tablet	oral use
United Kingdom	Winthrop Pharmaceuticals UK Limited, One Onslow Street, Guildford, Surrey GU1 4YS United Kingdom	Zolpidem Tartrate 10 mg tablets	10 mg	film-coated tablet	oral use

ANNEX II

List of the names, pharmaceutical forms, strengths of the medicinal products, route of administration and marketing authorisation holders in the Member States

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Austria	AstraZeneca Österreich GmbH, Schwarzenbergplatz 7, A-1037 Wien, Austria	Crestor 5 mg — Filmtable- tten	5 mg	Film coated tablets	Oral use
Austria	AstraZeneca Österreich GmbH, Schwarzenbergplatz 7, A-1037 Wien, Austria	Crestor 10 mg — Filmtable- tten	10 mg	Film coated tablets	Oral use
Austria	AstraZeneca Österreich GmbH, Schwarzenbergplatz 7, A-1037 Wien, Austria	Crestor 20 mg — Filmtable- tten	20 mg	Film coated tablets	Oral use
Austria	AstraZeneca Österreich GmbH, Schwarzenbergplatz 7, A-1037 Wien, Austria	Crestor 40 mg — Filmtable- tten	40 mg	Film coated tablets	Oral use
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels, Belgium	Crestor	5 mg	Film coated tablets	Oral use
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels, Belgium	Crestor	10 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels, Belgium	Crestor	20 mg	Film coated tablets	Oral use
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels, Belgium	Crestor	40 mg	Film coated tablets	Oral use
Bulgaria	AstraZeneca Pharmaceuticals AB, S-151 85 Södertälje, Sweden	Crestor	5 mg	Film coated tablets	Oral use
Bulgaria	AstraZeneca Pharmaceuticals AB, S-151 85 Södertälje, Sweden	Crestor	10 mg	Film coated tablets	Oral use
Bulgaria	AstraZeneca Pharmaceuticals AB, S-151 85 Södertälje, Sweden	Crestor	20 mg	Film coated tablets	Oral use
Croatia	AstraZeneca d.o.o. Radnička cesta 80 10000 Zagreb Croatia	Crestor 5 mg filmom ob- ložene tablete	5 mg	Film coated tablets	Oral use
Croatia	AstraZeneca d.o.o. Radnička cesta 80 10000 Zagreb Croatia	Crestor 10 mg filmom ob- ložene tablete	10 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Croatia	AstraZeneca d.o.o. Radnička cesta 80 10000 Zagreb Croatia	Crestor 20 mg filmom ob- ložene tablete	20 mg	Film coated tablets	Oral use
Croatia	AstraZeneca d.o.o. Radnička cesta 80 10000 Zagreb Croatia	Crestor 40 mg filmom ob- ložene tablete	40 mg	Film coated tablets	Oral use
Cyprus	AstraZeneca UK Limited, 2 Kingdom Street, London W2 6BD, United Kingdom	Crestor	5 mg	Film coated tablets	Oral use
Cyprus	AstraZeneca UK Limited, 2 Kingdom Street, London W2 6BD, United Kingdom	Crestor	10 mg	Film coated tablets	Oral use
Cyprus	AstraZeneca UK Limited, 2 Kingdom Street, London W2 6BD, United Kingdom	Crestor	20 mg	Film coated tablets	Oral use
Cyprus	AstraZeneca UK Limited, 2 Kingdom Street, London W2 6BD, United Kingdom	Crestor	40 mg	Film coated tablets	Oral use
Czech Republic	AstraZeneca UK Limited, 2 Kingdom Street London W2 6BD United Kingdom	Crestor 5 mg	5 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Czech Republic	AstraZeneca UK Limited, 2 Kingdom Street London W2 6BD United Kingdom	Crestor 10 mg	10 mg	Film coated tablets	Oral use
Czech Republic	AstraZeneca UK Limited, 2 Kingdom Street London W2 6BD United Kingdom	Crestor 20 mg	20 mg	Film coated tablets	Oral use
Czech Republic	AstraZeneca UK Limited, 2 Kingdom Street London W2 6BD United Kingdom	Crestor 40 mg	40 mg	Film coated tablets	Oral use
Denmark	AstraZeneca A/S Arne Jacobsens Allé 13 2300 København S Denmark	Crestor	5 mg	Film coated tablets	Oral use
Denmark	AstraZeneca A/S Arne Jacobsens Allé 13 2300 København S Denmark	Crestor	10 mg	Film coated tablets	Oral use
Denmark	AstraZeneca A/S Arne Jacobsens Allé 13 2300 København S Denmark	Crestor	20 mg	Film coated tablets	Oral use
Denmark	AstraZeneca A/S Arne Jacobsens Allé 13 2300 København S Denmark	Crestor	40 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Estonia	AstraZeneca UK Ltd. 2 Kingdom Street, London W2 6BD, United Kingdom	Crestor	5 mg	Film coated tablets	Oral use
Estonia	AstraZeneca UK Ltd. 2 Kingdom Street, London W2 6BD, United Kingdom	Crestor	10 mg	Film coated tablets	Oral use
Estonia	AstraZeneca UK Ltd. 2 Kingdom Street, London W2 6BD, United Kingdom	Crestor	20 mg	Film coated tablets	Oral use
Finland	AstraZeneca Oy Itsehallintokuja 4 02600 Espoo Finland	Crestor	5 mg	Film coated tablets	Oral use
Finland	AstraZeneca Oy Itsehallintokuja 4 02600 Espoo Finland	Crestor	10 mg	Film coated tablets	Oral use
Finland	AstraZeneca Oy Itsehallintokuja 4 02600 Espoo Finland	Crestor	20 mg	Film coated tablets	Oral use
Finland	AstraZeneca Oy Itsehallintokuja 4 02600 Espoo Finland	Crestor	40 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
France	AstraZeneca 1, Place Renault 92844 Rueil-Malmaison Cedex, France	Crestor	5 mg	Film coated tablets	Oral use
France	AstraZeneca 1, Place Renault 92844 Rueil-Malmaison Cedex, France	Crestor	10 mg	Film coated tablets	Oral use
France	AstraZeneca 1, Place Renault 92844 Rueil-Malmaison Cedex, France	Crestor	20 mg	Film coated tablets	Oral use
Germany	AstraZeneca GmbH, 22876 Wedel, Germany	CRESTOR 5 mg Filmtable- tten	5 mg	Film coated tablets	Oral use
Germany	AstraZeneca GmbH, 22876 Wedel, Germany	CRESTOR 10 mg Filmtable- tten	10 mg	Film coated tablets	Oral use
Germany	AstraZeneca GmbH, 22876 Wedel, Germany	CRESTOR 20 mg Filmtable- tten	20 mg	Film coated tablets	Oral use
Germany	AstraZeneca GmbH, 22876 Wedel, Germany	CRESTOR 40 mg Filmtable- tten	40 mg	Film coated tablets	Oral use
Greece	AstraZeneca S.A 4 Theotokopoulou & Astronafion str 151 25 Maroussi, Athens Greece	Crestor	5 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Greece	AstraZeneca SA 4 Theotokopoulou & Astronafton str 151 25 Maroussi, Athens Greece	Crestor	10 mg	Film coated tablets	Oral use
Greece	AstraZeneca SA 4 Theotokopoulou & Astronafton str 151 25 Maroussi, Athens Greece	Crestor	20 mg	Film coated tablets	Oral use
Greece	AstraZeneca SA 4 Theotokopoulou & Astronafton str 151 25 Maroussi, Athens Greece	Crestor	40 mg	Film coated tablets	Oral use
Hungary	AstraZeneca Kft., 1113 Budapest, Bocskai út 134-146., Hungary	Crestor 5 mg filmtabletta	5 mg	Film coated tablets	Oral use
Hungary	AstraZeneca Kft., 1113 Budapest, Bocskai út 134-146., Hungary	Crestor 10 mg filmtabletta	10 mg	Film coated tablets	Oral use
Hungary	AstraZeneca Kft., 1113 Budapest, Bocskai út 134-146., Hungary	Crestor 20 mg filmtabletta	20 mg	Film coated tablets	Oral use
Iceland	AstraZeneca A/S Arne Jacobsens Allé 13 2300 København S Denmark	Crestor	5 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Iceland	AstraZeneca A/S Arne Jacobsens Allé 13 2300 København S Denmark	Crestor	10 mg	Film coated tablets	Oral use
Iceland	AstraZeneca A/S Arne Jacobsens Allé 13 2300 København S Denmark	Crestor	20 mg	Film coated tablets	Oral use
Iceland	AstraZeneca A/S Arne Jacobsens Allé 13 2300 København S Denmark	Crestor	40 mg	Film coated tablets	Oral use
Ireland	AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, United Kingdom	Crestor	5 mg	Film coated tablets	Oral use
Ireland	AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, United Kingdom	Crestor	10 mg	Film coated tablets	Oral use
Ireland	AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, United Kingdom	Crestor	20 mg	Film coated tablets	Oral use
Ireland	AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, United Kingdom	Crestor	40 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Italy	AstraZeneca S.p.A. Palazzo Volta, Via F. Sforza 20080 Basiglio (MI), Italy	Crestor	5 mg	Film coated tablets	Oral use
Italy	AstraZeneca S.p.A. Palazzo Volta, Via F. Sforza 20080 Basiglio (MI), Italy	Crestor	10 mg	Film coated tablets	Oral use
Italy	AstraZeneca S.p.A. Palazzo Volta, Via F. Sforza 20080 Basiglio (MI), Italy	Crestor	20 mg	Film coated tablets	Oral use
Italy	AstraZeneca S.p.A. Palazzo Volta, Via F. Sforza 20080 Basiglio (MI), Italy	Crestor	40 mg	Film coated tablets	Oral use
Italy	AstraZeneca S.p.A. Palazzo Volta, Via F. Sforza 20080 Basiglio (MI), Italy	Cirantan	5 mg	Film coated tablets	Oral use
Italy	AstraZeneca S.p.A. Palazzo Volta, Via F. Sforza 20080 Basiglio (MI), Italy	Cirantan	10 mg	Film coated tablets	Oral use
Italy	AstraZeneca S.p.A. Palazzo Volta, Via F. Sforza 20080 Basiglio (MI), Italy	Cirantan	20 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Italy	AstraZeneca S.p.A. Palazzo Volta, Via F. Sforza 20080 Basiglio (MI), Italy	Cirantan	40 mg	Film coated tablets	Oral use
Italy	AstraZeneca S.p.A. Palazzo Volta, Via F. Sforza 20080 Basiglio (MI), Italy	Provisacor	5 mg	Film coated tablets	Oral use
Italy	AstraZeneca S.p.A. Palazzo Volta, Via F. Sforza 20080 Basiglio (MI), Italy	Provisacor	10 mg	Film coated tablets	Oral use
Italy	AstraZeneca S.p.A. Palazzo Volta, Via F. Sforza 20080 Basiglio (MI), Italy	Provisacor	20 mg	Film coated tablets	Oral use
Italy	AstraZeneca S.p.A. Palazzo Volta, Via F. Sforza 20080 Basiglio (MI), Italy	Provisacor	40 mg	Film coated tablets	Oral use
Italy	Simesa S.p.A. Palazzo Galileo, Via F. Sforza, 20080 Basiglio (MI), Italy	Simestat	5 mg	Film coated tablets	Oral use
Italy	Simesa S.p.A. Palazzo Galileo, Via F. Sforza, 20080 Basiglio (MI), Italy	Simestat	10 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Italy	Simesa S.P.A. Palazzo Galileo, Via F. Sforza, 20080 Basiglio (MI), Italy	Simestat	20 mg	Film coated tablets	Oral use
Italy	Simesa S.P.A. Palazzo Galileo, Via F. Sforza, 20080 Basiglio (MI), Italy	Simestat	40 mg	Film coated tablets	Oral use
Latvia	AstraZeneca UK Limited 2 Kingdom Street London W2 6BD United Kingdom	Crestor 5 mg apvalkotās tabletes	5 mg	Film coated tablets	Oral use
Latvia	AstraZeneca UK Limited 2 Kingdom Street London W2 6BD United Kingdom	Crestor 10 mg apvalkotās tabletes	10 mg	Film coated tablets	Oral use
Latvia	AstraZeneca UK Limited 2 Kingdom Street London W2 6BD United Kingdom	Crestor 20 mg apvalkotās tabletes	20 mg	Film coated tablets	Oral use
Latvia	AstraZeneca UK Limited 2 Kingdom Street London W2 6BD United Kingdom	Crestor 40 mg apvalkotās tabletes	40 mg	Film coated tablets	Oral use
Lithuania	AstraZeneca UK Limited 2 Kingdom Street London W2 6BD United Kingdom	Crestor	5 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Lithuania	AstraZeneca UK Limited 2 Kingdom Street London W2 6BD United Kingdom	Crestor	10 mg	Film coated tablets	Oral use
Lithuania	AstraZeneca UK Limited 2 Kingdom Street London W2 6BD United Kingdom	Crestor	20 mg	Film coated tablets	Oral use
Lithuania	AstraZeneca UK Limited 2 Kingdom Street London W2 6BD United Kingdom	Crestor	40 mg	Film coated tablets	Oral use
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels, Belgium	Crestor	5 mg	Film coated tablets	Oral use
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels, Belgium	Crestor	10 mg	Film coated tablets	Oral use
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels, Belgium	Crestor	20 mg	Film coated tablets	Oral use
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels, Belgium	Crestor	40 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Malta	AstraZeneca UK Limited 2 Kingdom Street London W2 6BD United Kingdom	Crestor	5 mg	Film coated tablets	Oral use
Malta	AstraZeneca UK Limited 2 Kingdom Street London W2 6BD United Kingdom	Crestor	10 mg	Film coated tablets	Oral use
Malta	AstraZeneca UK Limited 2 Kingdom Street London W2 6BD United Kingdom	Crestor	20 mg	Film coated tablets	Oral use
Malta	AstraZeneca UK Limited 2 Kingdom Street London W2 6BD United Kingdom	Crestor	40 mg	Film coated tablets	Oral use
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Crestor	5 mg	Film coated tablets	Oral use
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Crestor	10 mg	Film coated tablets	Oral use
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Crestor	20 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Crestor	40 mg	Film coated tablets	Oral use
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Cirantan	5 mg	Film coated tablets	Oral use
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Cirantan	10 mg	Film coated tablets	Oral use
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Cirantan	20 mg	Film coated tablets	Oral use
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Cirantan	40 mg	Film coated tablets	Oral use
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Provisacor	5 mg	Film coated tablets	Oral use
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Provisacor	10 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Provisacor	20 mg	Film coated tablets	Oral use
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Provisacor	40 mg	Film coated tablets	Oral use
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Rosuvastatin AstraZeneca	5 mg	Film coated tablets	Oral use
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Rosuvastatin AstraZeneca	10 mg	Film coated tablets	Oral use
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Rosuvastatin AstraZeneca	20 mg	Film coated tablets	Oral use
The Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Rosuvastatin AstraZeneca	40 mg	Film coated tablets	Oral use
Norway	AstraZeneca AS Postboks 6050, Ettrestad 0601 Oslo Norway	Crestor	5 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Norway	AstraZeneca AS Postboks 6050, Etterstad 0601 Oslo Norway	Crestor	10 mg	Film coated tablets	Oral use
Norway	AstraZeneca AS Postboks 6050, Etterstad 0601 Oslo Norway	Crestor	20 mg	Film coated tablets	Oral use
Norway	AstraZeneca AS Postboks 6050, Etterstad 0601 Oslo Norway	Crestor	40 mg	Film coated tablets	Oral use
Poland	AstraZeneca AB, S-151 85 Södertälje, Sweden	Crestor	5 mg	Film coated tablets	Oral use
Poland	AstraZeneca AB, S-151 85 Södertälje, Sweden	Crestor	10 mg	Film coated tablets	Oral use
Poland	AstraZeneca AB, S-151 85 Södertälje, Sweden	Crestor	20 mg	Film coated tablets	Oral use
Poland	AstraZeneca AB, S-151 85 Södertälje, Sweden	Crestor	40 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, 7 Queluz de Baixo 2730-097 Barcarena Portugal	Crestor 5 mg	5 mg	Film coated tablets	Oral use
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, 7 Queluz de Baixo 2730-097 Barcarena Portugal	Crestor 10 mg	10 mg	Film coated tablets	Oral use
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, 7 Queluz de Baixo 2730-097 Barcarena Portugal	Crestor 20 mg	20 mg	Film coated tablets	Oral use
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, 7 Queluz de Baixo 2730-097 Barcarena Portugal	Crestor 40 mg	40 mg	Film coated tablets	Oral use
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, 7, Queluz de Baixo 2730-097 Barcarena Portugal	Visacor 5 mg	5 mg	Film coated tablets	Oral use
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, 7, Queluz de Baixo 2730-097 Barcarena Portugal	Visacor 10 mg	10 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, 7, Queluz de Baixo 2730-097 Barcarena Portugal	Visacor 20 mg	20 mg	Film coated tablets	Oral use
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, 7, Queluz de Baixo 2730-097 Barcarena Portugal	Visacor 40 mg	40 mg	Film coated tablets	Oral use
Romania	AstraZeneca UK Limited 2 Kingdom Street, London W2 6BD, United Kingdom	Crestor 5 mg comprimate filmate	5 mg	Film coated tablets	Oral use
Romania	AstraZeneca UK Limited 2 Kingdom Street, London W2 6BD, United Kingdom	Crestor 10 mg comprimate filmate	10 mg	Film coated tablets	Oral use
Romania	AstraZeneca UK Limited 2 Kingdom Street, London W2 6BD, United Kingdom	Crestor 20 mg comprimate filmate	20 mg	Film coated tablets	Oral use
Romania	AstraZeneca UK Limited 2 Kingdom Street, London W2 6BD, United Kingdom	Crestor 40 mg comprimate filmate	40 mg	Film coated tablets	Oral use
Slovak Republic	AstraZeneca UK Ltd 2 Kingdom Street London, W2 6BD, United Kingdom	CRESTOR 5 mg	5 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	AstraZeneca UK Ltd 2 Kingdom Street London, W2 6BD, United Kingdom	CRESTOR 10 mg	10 mg	Film coated tablets	Oral use
Slovak Republic	AstraZeneca UK Ltd 2 Kingdom Street London, W2 6BD, United Kingdom	CRESTOR 20 mg	20 mg	Film coated tablets	Oral use
Slovak Republic	AstraZeneca UK Ltd 2 Kingdom Street London, W2 6BD, United Kingdom	CRESTOR 40 mg	40mg	Film coated tablets	Oral use
Slovenia	AstraZeneca UK Limited 2 Kingdom Street London, W2 6BD, United Kingdom	Crestor 5 mg filmsko ob- ložene tablete	5 mg	Film coated tablets	Oral use
Slovenia	AstraZeneca UK Limited 2 Kingdom Street London, W2 6BD, United Kingdom	Crestor 10 mg filmsko ob- ložene tablete	10 mg	Film coated tablets	Oral use
Slovenia	AstraZeneca UK Limited 2 Kingdom Street London, W2 6BD, United Kingdom	Crestor 20 mg filmsko ob- ložene tablete	20 mg	Film coated tablets	Oral use
Slovenia	AstraZeneca UK Limited 2 Kingdom Street London, W2 6BD, United Kingdom	Crestor 40 mg filmsko ob- ložene tablete	40 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Spain	AstraZeneca Farmacéutica Spain, S.A. Parque Norte.Edificio Roble. C/Serrano Galvache 56, 28033 Madrid, Spain.	Crestor 5 mg comprimidos recubiertos con película	5 mg	Film coated tablets	Oral use
Spain	AstraZeneca Farmacéutica Spain, S.A. Parque Norte.Edificio Roble. C/Serrano Galvache 56, 28033 Madrid, Spain.	Crestor 10 mg comprimidos recubiertos con película	10 mg	Film coated tablets	Oral use
Spain	AstraZeneca Farmacéutica Spain, S.A. Parque Norte.Edificio Roble. C/Serrano Galvache 56, 28033 Madrid, Spain.	Crestor 20 mg comprimidos recubiertos con película	20 mg	Film coated tablets	Oral use
Spain	AstraZeneca Farmacéutica Spain, S.A. Parque Norte.Edificio Roble. C/Serrano Galvache 56, 28033 Madrid, Spain.	Crestor 40 mg comprimidos recubiertos con película	40 mg	Film coated tablets	Oral use
Spain	AstraZeneca Farmacéutica Spain, S.A. Parque Norte.Edificio Roble. C/Serrano Galvache 56, 28033 Madrid, Spain.	Provisacor 5 mg comprimidos recubiertos con película	5 mg	Film coated tablets	Oral use
Spain	AstraZeneca Farmacéutica Spain, S.A. Parque Norte.Edificio Roble. C/Serrano Galvache 56, 28033 Madrid, Spain.	Provisacor 10 mg comprimidos recubiertos con película	10 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Spain	AstraZeneca Farmacéutica Spain, S.A. Parque Norte.Edificio Roble. C/Serrano Galvache 56, 28033 Madrid, Spain.	Provisacor 20 mg comprimidos recubiertos con película	20 mg	Film coated tablets	Oral use
Spain	AstraZeneca Farmacéutica Spain, S.A. Parque Norte.Edificio Roble. C/Serrano Galvache 56, 28033 Madrid, Spain.	Provisacor 40 mg comprimidos recubiertos con película	40 mg	Film coated tablets	Oral use
Sweden	AstraZeneca AB, S-151 85 Södertälje Sweden	Crestor	5 mg	Film coated tablets	Oral use
Sweden	AstraZeneca AB, S-151 85 Södertälje Sweden	Crestor	10 mg	Film coated tablets	Oral use
Sweden	AstraZeneca AB, S-151 85 Södertälje Sweden	Crestor	20 mg	Film coated tablets	Oral use
Sweden	AstraZeneca AB, S-151 85 Södertälje Sweden	Crestor	40 mg	Film coated tablets	Oral use
United Kingdom	AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, United Kingdom	Crestor	5 mg	Film coated tablets	Oral use
United Kingdom	AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, United Kingdom	Crestor	10 mg	Film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
United Kingdom	AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, United Kingdom	Crestor	20 mg	Film coated tablets	Oral use
United Kingdom	AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, United Kingdom	Crestor	40 mg	Film coated tablets	Oral use