



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

05 September 2013
EMA/541119/2013
Patient Health Protection

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for bromocriptine-containing medicinal products indicated in the "*prevention or suppression of physiological lactation in the immediate post-partum period and in the late post-partum period*"

Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure number: EMEA/H/A-31/1379



Member State in EU/EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	Meda Pharma GmbH, Guglgasse 15/II. Stock, 1110 Wien, Austria	Parlodel 2,5 mg - Tabletten	2.5 mg	tablet	oral use
Belgium	Meda Pharma s.a. Chaussée de la Hulpe 166 1170 Brussels Belgium	Parlodel	2.5 mg	tablet	oral use
Belgium	Meda Pharma s.a. Chaussée de la Hulpe 166 1170 Brussels Belgium	Parlodel 5 mg	5 mg	capsule, hard	oral use
Belgium	Meda Pharma s.a. Chaussée de la Hulpe 166 1170 Brussels Belgium	Parlodel 10 mg	10 mg	capsule, hard	oral use
Bulgaria	Sopharma AD 16 "Iliensko shose" Str. Sofia 1220 Bulgaria	Bromocriptine Sopharma	2.5 mg	tablet	oral use
Bulgaria	Medochemie Ltd., 1-10 Astronafton Str. Limassol 3505 Cyprus	Medocriptine	2.5 mg	tablet	oral use
Croatia	Sandoz d.o.o. Maksimirska 120/V, Zagreb 10 000 Croatia	Bromergon 2,5 mg tablete	2.5 mg	tablet	oral use

Member State in EU/EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Cyprus	Codal Synto Ltd 33 Theklas Lysiotti street Dorothea Building 6th floor Lemesos 3508 Cyprus	Pirodal	2.5 mg	tablet	oral use
Cyprus	Remedica Ltd Aharnon Street ,Limassol Industrial Estate Lemesos 3508 Cyprus	Brameston	2.5 mg	tablet	oral use
Cyprus	Medochemie Ltd Constantinoupoleos 1-10 Street Lemesos 3501 Cyprus	Medocriptine	2.5 mg	tablet	oral use
Czech Republic	MEDA Pharma s.r.o. Kodaňská 1441/46 110 00 Prague 10 Czech Republic	Parlodel	2.5 mg	tablet	oral use
Czech Republic	Medochemie Ltd. Konstantinoupoleos Str. 1_10 3011 Limassol – Tsiflikoudia Cyprus	Medocriptine	2.5 mg	tablet	oral use
Denmark	Meda AS, Solvang 8, DK-3450 Allerød, Denmark	Parlodel	10 mg	capsule, hard	oral use
Denmark	Meda AS, Solvang 8, DK-3450 Allerød, Denmark	Parlodel	5 mg	capsule, hard	oral use
Denmark	Meda AS, Solvang 8, DK-3450 Allerød, Denmark	Parlodel	2.5 mg	tablet	oral use

Member State in EU/EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Estonia	Gedeon Richter Plc. Gyömrői ut 19-21 1103 Budapest Hungary	BROMOCRIPTIN- RICHTER	2.5 mg	tablet	oral use
Finland	Meda Oy Vaisalantie 4 02130 Espoo Finland	PARLODEL	2.5 mg	tablet	oral use
France	MEDA PHARMA 25, boulevard de l'Amiral Bruix, 75016 Paris France	PARLODEL 2,5 mg inhibition de la lactation	2.5 mg	tablet	oral use
France	SANOFI AVENTIS FRANCE 1-13 boulevard Romain Rolland 75014 PARIS France	BROMOCRIPTINE ZENTIVA 2,5 mg INHIBITION DE LA LACTATION	2.5 mg	tablet	oral use
Germany	AbZ-Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Bromocriptin AbZ 2,5 mg	2.5 mg	tablet	oral use
Germany	betapharm Arzneimittel GmbH Kobelweg 95 86156 Augsburg Germany	Bromocriptin beta 2,5	2.5 mg	tablet	oral use
Germany	CT Arzneimittel GmbH Graf-Arco-Str. 3 89079 Ulm germany	bromocriptin-ct 2,5mg Tabletten	2.5 mg	tablet	oral use
Germany	Hexal AG Industriestr. 25 83607 Holzkirchen Germany	Bromocriptin HEXAL 2,5mg Tabletten	2.5 mg	tablet	oral use

Member State in EU/EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	MEDA Pharma GmbH & Co. KG Benzstr. 1 61352 Bad Homburg Germany	Pravidel 2,5 mg Tabletten	2.5 mg	tablet	oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Bromocriptin- ratiopharm 2,5mg Tabletten	2.5 mg	tablet	oral use
Greece	MEDA PHARMACEUTICALS S.A., GREECE 3 Evrytanias Str., Halandri, 15231, Attiki, Greece	Parlodel	2.5 mg	tablet	oral use
Greece	MEDA PHARMACEUTICALS S.A., GREECE 3 Evrytanias Str., Halandri, 15231, Attiki, Greece	Parlodel	5 mg	capsule, hard	oral use
Greece	MEDA PHARMACEUTICALS S.A., GREECE 3 Evrytanias Str., Halandri, 15231, Attiki, Greece	Parlodel	10 mg	capsule, hard	oral use
Hungary	Gedeon Richter Plc Gyömrői út 19-21. H-1103 Budapest Hungary	Bromocriptin- Richter 2,5 mg tableta	2.5 mg	tablet	oral use
Ireland	Meda Health Sales Ireland Limited Unit 34/35, Block A Dunboyne Business Park Dunboyne Co. Meath Ireland	Parlodel 2.5 mg Tablets	2.5 mg	tablet	oral use

Member State in EU/EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Meda Health Sales Ireland Limited Unit 34/35, Block A Dunboyne Business Park Dunboyne Co. Meath Ireland	Parlodel 5mg Hard Capsules.	5 mg	capsule, hard	oral use
Italy	MEDA PHARMA S.P.A. Viale Brenta 18, 20139 Milano Italy	PARLODEL	2.5 mg	tablet	oral use
Italy	MEDA PHARMA S.P.A. Viale Brenta 18, 20139 Milano Italy	PARLODEL	5 mg	capsule, hard	oral use
Italy	MEDA PHARMA S.P.A. Viale Brenta 18, 20139 Milano Italy	PARLODEL	10 mg	capsule, hard	oral use
Italy	TEVA ITALIA S.R.L. Via Messina 38, 20154 Milano Italy	BROMOCRIPTINA DOROM	2.5 mg	tablet	oral use
Lithuania	Gedeon Richter Plc. Gyömrői út 19-21 1103 Budapest, Hungary	BROMOCRIPTIN- RICTER	2.5 mg	tablet	oral use
Luxembourg	MEDA Pharma GmbH & Co. KG Benzstraße 1 61352 Bad Homburg Germany	Pravidel	2.5 mg	tablet	oral use
Norway	Meda AS, Askerveien 61, Postboks 194, 1371 Asker Norway	Parlodel	2.5 mg	tablet	oral use

Member State in EU/EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Poland	Sandoz GmbH Biochemiestrasse 10 Kundl 6250 Tyrol Austria	Bromergon	2.5 mg	tablet	oral use
Poland	Farmaceutyczna Spółdzielnia Pracy FILOFARM ul. Pułaskiego 39 85-619 Bydgoszcz Poland	Bromocorn	2.5 mg	tablet	oral use
Poland	Meda Aktiebolag Pipers vag 2 170 09 Solana Box 906 Sweden	Parlodel	2.5 mg	tablet	oral use
Portugal	Meda Pharma - Produtos farmacêuticos, S.A. PRT Rua do Centro Cultural, 13 Lisboa, 1749-066 Portugal	Parlodel	5 mg	capsule	oral use
Portugal	Meda Pharma - Produtos farmacêuticos, S.A. Rua do Centro Cultural, 13 Lisboa, 1749-066 Portugal	Parlodel	10 mg	capsule	oral use
Portugal	Meda Pharma - Produtos farmacêuticos, S.A. Rua do Centro Cultural, 13 Lisboa, 1749-066 Portugal	Parlodel	2.5 mg	tablet	oral use
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Bromocriptina Generis 2,5 mg comprimidos	2.5 mg	tablet	oral use

Member State in EU/EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Romania	S.C. BIOFARM S.A. Str. Logofăt Tăutu nr. 99, sector 3, Bucureşti, Romania	BROMOCRIPTIN	2.5 mg	coated tablet	oral use
Slovak Republic	MEDA Pharma s.r.o. Kodaňská 1441/46 100 00 Praha 10 Czech Republic	Parlodel	2.5 mg	tablet	oral use
Slovak Republic	Medochemie Ltd. 1-10 Constantinoupoleos St. 3011 Limassol, Cyprus	MEDOCRIPTINE 2,5 mg	2.5 mg	tablet	oral use
Slovenia	Lek farmacevtska družba d.d., Verovškova 57, 1000 Ljubljana, Slovenia	Bromergon 2,5 mg tablete	2.5 mg	tablet	oral use
Spain	MEDA PHARMA, S.A.U. Avda. Castilla 2, Edificio Berlín 2ª planta Parque Empresarial San Fernando 28830 San Fernando de Henares (Madrid) Spain	Parlodel 2,5 mg comprimidos	2.5 mg	tablet	oral use
Sweden	Meda AB Box 906 170 09 Solna Sweden	Pravidel	2.5 mg	tablet	oral use
Sweden	Meda AB Box 906 170 09 Solna Sweden	Pravidel	10 mg	capsule, hard	oral use

Member State in EU/EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Sweden	Meda AB Box 906 170 09 Solna Sweden	Pravidel	5 mg	capsule, hard	oral use
The Netherlands	Meda Pharma B.V. Krijgsman 20 1186 DM AMSTELVEEN The Netherlands	Parlodel 10 mg capsules	10 mg	capsule, hard	oral use
The Netherlands	Meda Pharma B.V. Krijgsman 20 1186 DM AMSTELVEEN The Netherlands	Parlodel 2,5 mg	2.5 mg	tablet	oral use
The Netherlands	Meda Pharma B.V. Krijgsman 20 1186 DM AMSTELVEEN The Netherlands	Parlodel 5 mg capsules	5 mg	capsule, hard	oral use
United Kingdom	Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex BN22 9AG, United Kingdom	Teva UK Bromocriptine Tablets	2.5 mg	tablet	oral use
United Kingdom	Meda Pharmaceuticals Limited, Skyway House, Parsonage Road, Takeley, Bishops Stortford CM22 6PU, United Kingdom	Parlodel 1mg Tablets	1 mg	tablet	oral use

Member State in EU/EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Meda Pharmaceuticals Limited, Skyway House, Parsonage Road, Takeley, Bishops Stortford CM22 6PU, United Kingdom	Parlodel 2.5mg Tablets	2.5 mg	tablet	oral use
United Kingdom	Meda Pharmaceuticals Limited, Skyway House, Parsonage Road, Takeley, Bishops Stortford CM22 6PU, United Kingdom	Parlodel 5mg Tablets	5 mg	capsule	oral use
United Kingdom	Meda Pharmaceuticals Limited, Skyway House, Parsonage Road, Takeley, Bishops Stortford CM22 6PU, United Kingdom	Parlodel 10mg Tablets	10 mg	capsule	oral use