



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 November 2015
EMA/230130/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: cabergoline

Procedure no.: PSUSA/00000477/201503



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Actualene		033359011 \$ 033359023 \$ 033359035	Pfizer Italia S.R.L.	Italy
Cabarsuss	SE/H/0900/001	42521	Hexal A/S	Sweden
Cabarsuss	SE/H/0900/002 \$ SE/H/0900/003	42522 \$ 42523	Hexal A/S	Sweden
Cabarsuss	SE/H/0900/004	45932	Hexal A/S	Sweden
Cabaser		031128010 \$ 031128022	Pfizer Italia S.R.L.	Italy
Cabaser		11957	Pfizer Oy	Finland
Cabaser		12509 \$ 12510	Pfizer Ab	Sweden
Cabaser		18071 \$ 18072	Pfizer Aps	Denmark
Cabaser		95-1396 \$ 95-1397	Pfizer As	Norway
Cabaser		PA 822/114/1 \$ PA 822/114/2	Pfizer Healthcare Ireland	Ireland
Cabaser		PL 00057/0936 \$ PL 00057/0937	Pfizer Limited	United Kingdom
Cabaseril		1-23067 \$ 1-23068	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria
Cabaseril		43569.00.00 \$ 43569.01.00	Pharmacia Gmbh	Germany
Cabergolin 1 A Pharma	SE/H/0901/001	77744.00.00	1 A Pharma Gmbh	Germany
Cabergolin 1 A Pharma	SE/H/0901/003	77746.00.00	1 A Pharma Gmbh	Germany
Cabergolin 1 A Pharma	SE/H/0901/004	84712.00.00	1 A Pharma Gmbh	Germany
Cabergolin Dura	DE/H/1964/001 \$ DE/H/1964/002 \$ DE/H/1964/003	66155.00.00 \$ 66156.00.00 \$ 66157.00.00	Mylan Dura Gmbh	Germany
Cabergolin Hexal	SE/H/0650/001 \$ SE/H/0900/001	65487.00.00 \$ 77747.00.00	Hexal Ag	Germany

Cabergolin Hexal	SE/H/0650/002 \$ SE/H/0650/003 \$ SE/H/0900/002 \$ SE/H/0900/003	65488.00.00 \$ 65489.00.00 \$ 77748.00.00 \$ 77749.00.00	Hexal Ag	Germany
Cabergolin Hexal	SE/H/0651/001	39573	Hexal A/S	Denmark
Cabergolin Hexal	SE/H/0900/004	84737.00.00	Hexal Ag	Germany
Cabergolin Hexal	SE/H/0901/002	77745.00.00	1 A Pharma Gmbh	Germany
Cabergolin Teva	DK-H-0988-001-003-DC	39287	Teva Denmark A/S	Denmark
Cabergolin Teva	DK-H-0988-001-003-DC	39288 \$ 39289	Teva Denmark A/S	Denmark
Cabergolin-Teva	SE-H-0570-001-003-MR	66779.00.00	Teva Gmbh	Germany
Cabergolin-Teva	SE-H-0570-001-003-MR	66780.00.00 \$ 66781.00.00	Teva Gmbh	Germany
Cabergolina Ratiopharm	SE-H-0648-001-003	037576016 \$ 037576028	Ratiopharm Gmbh	Italy
Cabergolina Ratiopharm	SE-H-0648-001-003	037576220 \$ 037576321/M \$ 037576384	Ratiopharm Gmbh	Italy
Cabergolina Sandoz	SE/H/0651/001	037921018/M \$ 037921020/M \$ 037921032/M \$ 037921044/M \$ 037921057/M \$ 037921069/M \$ 037921071/M \$ 037921083/M \$ 037921095/M \$ 037921107/M \$ 037921119/M \$ 037921121/M \$ 037921133/M \$ 037921145/M \$ 037921158/M \$ 037921160/M \$ 037921172/M	Sandoz S.P.A.	Italy

Cabergolina Sandoz	SE/H/0651/002 \$ SE/H/0651/003	037921184 \$ 037921196 \$ 037921208 \$ 037921210 \$ 037921222 \$ 037921234 \$ 037921246 \$ 037921259 \$ 037921261 \$ 037921273 \$ 037921285 \$ 037921297 \$ 037921309 \$ 037921311 \$ 037921323 \$ 037921335 \$ 037921347/M \$ 037921350/M \$ 037921362/M \$ 037921374/M \$ 037921386/M \$ 037921398/M \$ 037921400/M \$ 037921412/M \$ 037921424/M \$ 037921436/M \$ 037921448/M \$ 037921451/M \$ 037921463/M \$ 037921475/M \$ 037921487/M \$ 037921499/M	Sandoz S.P.A.	Italy
Cabergolina Sandoz Gmbh	SE/H/0899/001	042248017 \$ 042248029 \$ 042248031 \$ 042248043 \$ 042248056	Sandoz Gmbh	Italy
Cabergolina Sandoz Gmbh	SE/H/0899/002 \$ SE/H/0899/003	042248068 \$ 042248070 \$ 042248082 \$ 042248094 \$ 042248106 \$ 042248118 \$ 042248120 \$ 042248132 \$ 042248144 \$ 042248157 \$ 042248169 \$ 042248171 \$ 042248183 \$ 042248195 \$ 042248207 \$ 042248219 \$ 042248221 \$ 042248233 \$ 042248245 \$ 042248258 \$ 042248260 \$ 042248272 \$ 042248284 \$ 042248296 \$ 042248308 \$ 042248310	Sandoz Gmbh	Italy
Cabergolina Teva	DK-H-0988-001-004-DC	69669	Teva Pharma S.L.U.	Spain
Cabergolina Teva	DK-H-0988-001-004-DC	69686 \$ 69687	Teva Pharma S.L.U.	Spain
Cabergoline	UK-H-3014-001-003-MR	PL 00289/0988	Teva Uk Limited	United Kingdom
Cabergoline	UK-H-3014-001-003-MR	PL 00289/0989 \$ PL 00289/0990	Teva Uk Limited	United Kingdom

Cabergoline "sandoz"	SE/H/0899/001	51047	Sandoz A/S	Denmark
Cabergoline 0.5 Pch	SE-H-0570-001-003-MR	RVG 34176	Pharmachemie B.V.	Netherlands
Cabergoline 1a Farma	SE/H/0901/001	42524	1a Farma A/S	Sweden
Cabergoline 1a Farma	SE/H/0901/002 \$ SE/H/0901/003	42525 \$ 42526	1a Farma A/S	Sweden
Cabergoline 1a Farma	SE/H/0901/004	45933	1a Farma A/S	Sweden
Cabergoline Actavis Group Ptc Ehf.	UK/H/0955/001-004	PL 30306/0594 \$ PL 30306/0595 \$ PL 30306/0596	Actavis Group Ptc Ehf.	United Kingdom
Cabergoline Aurobindo	UK/H/0955/001	RVG 34200	Aurobindo Pharma B.V.	Netherlands
Cabergoline Ct	SE-H-0649-001-002-MR	66355.00.00 \$ 66356.00.00	Abz-Pharma Gmbh	Germany
Cabergoline Hexal	SE/H/0650/001	23633	Hexal A/S	Sweden
Cabergoline Hexal	SE/H/0650/002 \$ SE/H/0650/003	23634 \$ 23636	Hexal A/S	Sweden
Cabergoline Ratiopharm	SE-H-0648-001-003	037576168/M	Ratiopharm Gmbh	Italy
Cabergoline Ratiopharm	SE-H-0648-001-003	037576485/M	Ratiopharm Gmbh	Italy
Cabergoline Ratiopharm	SE-H-0648-001-003	23663	Ratiopharm Gmbh	Sweden
Cabergoline Ratiopharm	SE-H-0648-001-003	66339.00.00	Ratiopharm Gmbh	Germany
Cabergoline Ratiopharm	SE-H-0648-001-003 \$ SE-H-0648-001-004	23664 \$ 23665	Ratiopharm Gmbh	Sweden
Cabergoline Ratiopharm	SE-H-0648-001-003 \$ SE-H-0648-001-004	66340.00.00 \$ 66341.00.00	Ratiopharm Gmbh	Germany
Cabergoline Sandoz	SE/H/0899/001	RVG 105105	Sandoz B.V.	Netherlands
Cabergoline Sandoz	SE/H/0899/001	34009 269 447 8 0 \$ 34009 269 448 4 1 \$ 34009 269 449 0 2 \$ 34009 269 450 9 1 \$ 34009 584 454 7 7	Sandoz	France
Cabergoline Sandoz	SE/H/0899/001	42516	Sandoz A/S	Sweden
Cabergoline Sandoz	SE/H/0899/002 \$ SE/H/0899/003	42517 \$ 42518	Sandoz A/S	Sweden

Cabergoline Teva	DK-H-0988-001-004-DC	NL32890	Teva Santé	France
Cabergoline Teva	SE-H-0570-001-003-MR	2010060805 \$ 2010060806	Teva Pharma Belgium N.V.	Luxembourg
Cabergoline Teva	SE-H-0570-001-003-MR	18746	Teva Sweden Ab	Sweden
Cabergoline Teva	SE-H-0570-001-003-MR	18747 \$ 18748	Teva Sweden Ab	Sweden
Cabergoline Teva	SE-H-0570-001-003-MR	2012070100	Teva Pharma Belgium N.V.	Luxembourg
Cabergoline Teva	SE-H-0570-001-003-MR	BE291977	Teva Pharma Belgium N.V.	Belgium
Cabergoline Teva	SE-H-0570-001-003-MR	BE291986 \$ BE291995	Teva Pharma Belgium N.V.	Belgium
Cabergoline Teva	UK-H-3014-001-003-MR	MA615/01501	Teva Pharma B.V.	Malta
Cabergoline Teva	UK-H-3014-001-003-MR	MA615/01502	Teva Pharma B.V.	Malta
Cabergoline Teva	UK-H-3014-001-003-MR	MA615/01503	Teva Pharma B.V.	Malta
Cabergoline Teva	UK-H-3014-001-003-MR	20457 \$ 20458 \$ 20459	Teva Pharma B.V.	Cyprus
Cabergoline Teva Pharma	SE-H-0649-001-002-MR	23671 \$ 23672	Teva Pharma B.V.	Sweden
Cabergonicht	SE/H/0651/001	23651	Sandoz A/S	Sweden
Cabergonicht	SE/H/0651/002 \$ SE/H/0651/003	23652 \$ 23653	Sandoz A/S	Sweden
Cabest	SE-H-0570-001-003-MR	34/0500/06-S	Teva Pharmaceuticals Slovakia S.R.O	Slovakia
Dostinex		028988018 \$ 028988020 \$ 028988032	Pfizer Italia S.R.L.	Italy
Dostinex		04-0309	Pfizer Italia S.R.L.	Latvia
Dostinex		1-20438	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria
Dostinex		11079	Pfizer Oy	Finland
Dostinex		11522	Pfizer Ab	Sweden

Dostinex		14398	Pfizer Aps	Denmark
Dostinex		1999095389	Pfizer S.A. (Belgium)	Luxembourg
Dostinex		2398881 \$ 2398980 \$ 2399087	Laboratórios Pfizer, Lda.	Portugal
Dostinex		32411.00.00	Pharmacia Gmbh	Germany
Dostinex		44396/14-9-2009	Pfizer Hellas, A.E.	Greece
Dostinex		4863	Pfizer Europe Ma Eeig	Poland
Dostinex		54/277/96-C	Pfizer, Spol. S R.O.	Czech Republic
Dostinex		60.867	Pfizer, S.L.	Spain
Dostinex		7619/2006/01 \$ 7619/2006/02	Pfizer Europe Ma Eeig	Romania
Dostinex		7843	Pfizer As	Norway
Dostinex		910091 (IS)	Pfizer Aps	Iceland
Dostinex		BE 159817	Pfizer S.A. (Belgium)	Belgium
Dostinex		LT/1/01/1619/001 \$ LT/1/01/1619/002 \$ LT/1/01/1619/003	Pfizer Italia S.R.L.	Lithuania
Dostinex		MA505/01401	Pfizer Hellas S.A.	Malta
Dostinex		PA 822/126/1	Pfizer Healthcare Ireland	Ireland
Dostinex		PL 00057/0969	Pfizer Limited	United Kingdom
Dostinex		RVG 15375	Pfizer B.V.	Netherlands
Dostinex		S00641	Pfizer Hellas, A.E.	Cyprus
Dostinex		NL 19342	Pfizer Holding France (S.C.A.)	France
Sogilen		64.408 \$ 64.409	Pfizer, S.L.	Spain

Sostilar		2001016999	Pfizer S.A. (Belgium)	Luxembourg
Sostilar		BE168682	Pfizer S.A. (Belgium)	Belgium
достинекс		20030572	Pfizer Enterprises Sarl	Bulgaria