



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 October 2018
EMA/776464/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: cabergoline

Procedure no.: PSUSA/00000477/201803



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
Cabarsuss, 3 mg, Tablett	SE/H/0900/004	45932	HEXAL A/S	SE
Dostinex 0.5 mg Tablets	not available	PL 00057/0969	PFIZER LIMITED	UK
Cabaser 2 mg Tablets	not available	PL 00057/0937	PFIZER LIMITED	UK
Cabaser 1 mg Tablets	not available	PL 00057/0936	PFIZER LIMITED	UK
Dostinex 500 microgram Tablets	not available	PA 822/126/1	PFIZER HEALTHCARE IRELAND	IE
Cabaser 2 mg Tablet	not available	PA 822/114/2	PFIZER HEALTHCARE IRELAND	IE
Cabaser 1 mg Tablet	not available	PA 822/114/1	PFIZER HEALTHCARE IRELAND	IE
Sostilar 0,5 mg Tabletten Cabergolin	not available	BE168682	PFIZER S.A. (BELGIUM)	BE
CABASER 1 mg tabletti	not available	11957	PFIZER OY	FI

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
Dostinex 0,5 mg tabletti	not available	11079	PFIZER OY	FI
DOSTINEX 0,5 mg comprimés Cabergoline	not available	BE 159817	PFIZER S.A. (BELGIUM)	BE
DOSTINEX 0,5 mg Tabletten Cabergolin	not available	1999095389	PFIZER S.A. (BELGIUM)	LU
Sostilar 0,5 mg Tabletten Cabergolin	not available	2001016999	PFIZER S.A. (BELGIUM)	LU
Dostinex 0.5 mg Tablets	not available	MA505/01401	PFIZER HELLAS, A.E.	MT
DOSTINEX 0,5 mg, comprimate	not available	7619/2006/01	PFIZER EUROPE MA EEIG	RO
Dostinex 0,5 mg töflur	not available	910091	PFIZER APS	IS
Dostinex, tabletter	not available	14398	PFIZER APS	DK
DOSTINEX 500 mikrogramų tabletės	not available	LT/1/01/1619/001	PFIZER ITALIA S.R.L.	LT

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
Dostinex 0,5 mg tabletti	not available	11079	PFIZER OY	FI
DOSTINEX 0,5 mg comprimés Cabergoline	not available	BE 159817	PFIZER S.A. (BELGIUM)	BE
ДОСТИНЕКС 0,5 mg таблетки	not available	20030572	PFIZER ENTERPRISES SARL	BG
DOSTINEX, 0,5 mg, tabletki	not available	4863	PFIZER EUROPE MA EEIG	PL
Dostinex, tabletten 0,5 mg	not available	RVG 15375	PFIZER B.V.	NL
DOSTINEX 0,5 mg compresse	not available	028988020	PFIZER ITALIA S.R.L.	IT
CABASER 2 mg COMPRESSE	not available	031128022	PFIZER ITALIA S.R.L.	IT
Cabaseril® 1 mg - Tabletten	not available	1-23067	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Dostinex 0,5 mg comprimidos	not available	2398980	LABORATÓRIOS PFIZER, LDA.	PT

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
Cabaseril® 2 mg - Tabletten	not available	1-23068	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
ACTUALENE 0,5 mg compresse	not available	033359011	PFIZER ITALIA S.R.L.	IT
DOSTINEX 0,5 mg compresse	not available	028988018	PFIZER ITALIA S.R.L.	IT
Dostinex 0,5 mg comprimidos	not available	2398881	LABORATÓRIOS PFIZER, LDA.	PT
SOSTILAR 0,5 mg comprimés Cabergoline	not available	BE168682	PFIZER S.A. (BELGIUM)	BE
ACTUALENE 0,5 mg compresse	not available	033359023	PFIZER ITALIA S.R.L.	IT
CABASER 1 mg tabletti	not available	11957	PFIZER OY	FI
DOSTINEX 0,5 mg tablety	not available	54/277/96-C	PFIZER, SPOL. S R.O.	CZ
DOSTINEX 0,5 mg compresse	not available	028988032	PFIZER ITALIA S.R.L.	IT

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
CABASER 1 mg COMPRESSE	not available	031128010	PFIZER ITALIA S.R.L.	IT
Sogilen 2 mg comprimidos	not available	64.409	PFIZER, S.L.	ES
DOSTINEX 500 mikrogramų tabletės	not available	LT/1/01/1619/003	PFIZER ITALIA S.R.L.	LT
Dostinex 0,5 mg comprimidos	not available	2399087	LABORATÓRIOS PFIZER, LDA.	PT
ACTUALENE 0,5 mg compresse	not available	033359035	PFIZER ITALIA S.R.L.	IT
DOSTINEX 500 mikrogramų tabletės	not available	LT/1/01/1619/002	PFIZER ITALIA S.R.L.	LT
Dostinex 0,5 mg tabletter	not available	7843	PFIZER AS	NO
Cabaser 1 mg tabletter	not available	95-1396	PFIZER AS	NO
DOSTINEX 0,5 mg, comprimé	not available	34009 340 427 0 6	PFIZER HOLDING FRANCE	FR

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
DOSTINEX 0,5 mg comprimés Cabergoline	not available	1999095389	PFIZER S.A. (BELGIUM)	LU
SOSTILAR 0,5 mg comprimés Cabergoline	not available	2001016999	PFIZER S.A. (BELGIUM)	LU
Cabaser 2 mg tabletter	not available	95-1397	PFIZER AS	NO
DOSTINEX 0,5 mg, comprimé	not available	34009 340 428 7 4	PFIZER HOLDING FRANCE	FR
Dostinex® 0,5 mg Tabletten	not available	32411.00.00	PFIZER PHARMA PFE GMBH	DE
Cabaseril® 1 mg Tabletten	not available	43569.00.00	PFIZER PHARMA PFE GMBH	DE
Cabaseril® 2 mg Tabletten	not available	43569.01.00	PFIZER PHARMA PFE GMBH	DE
DOSTINEX 0,5 mg tabletes	not available	04-0309	PFIZER ITALIA S.R.L.	LV
Cabaser, tabletter	not available	18072	PFIZER APS	DK

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Cabaser, tableter	not available	18071	PFIZER APS	DK
DOSTINEX 0,5 mg, comprimate	not available	7619/2006/02	PFIZER EUROPE MA EEIG	RO
Dostinex® 0,5 mg - Tabletten	not available	1-20438	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Dostinex δισκία 0,5 mg	not available	44396/14-9-2009	PFIZER HELLAS, A.E.	GR
Dostinex 0,5 mg comprimidos	not available	60.867	PFIZER, S.L.	ES
Sogilen 1 mg comprimidos	not available	64.408	PFIZER, S.L.	ES
DOSTINEX 0,5 mg tablete	not available	UP/I-530-09/12-01/451	PFIZER CROATIA D.O.O.	HR
Dostinex 0,5 mg tableter	not available	11522	PFIZER AB	SE
Cabaser 1 mg tableter	not available	12509	PFIZER AB	SE

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
Cabaser 2 mg tableter	not available	12510	PFIZER AB	SE
DOSTINEX 0,5 mg tabletten Cabergoline	not available	BE159817	PFIZER S.A. (BELGIUM)	BE
SOSTILAR 0,5 mg tabletten Cabergoline	not available	BE168682	PFIZER S.A. (BELGIUM)	BE