



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 October 2019
EMA/645069/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: cabergoline

Procedure no.: PSUSA/00000477/201903

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Classified as public by the European Medicines Agency

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
Cabergoline 1A Farma, 3 mg, Tablett	SE/H/0901/004	45933	1A FARMA A/S	SE
Dostinex® 0,5 mg Tabletten	not available	32411.00.00	PFIZER PHARMA PFE GMBH	DE
Cabarsuss, 3 mg, Tablett	SE/H/0900/004	45932	HEXAL A/S	SE
DOSTINEX 0,5 mg tablety	not available	54/277/96-C	PFIZER, SPOL. S R.O.	CZ
Dostinex 0,5 mg comprimidos	not available	60.867	PFIZER, S.L.	ES
Dostinex 500 microgram Tablets	not available	PA 822/126/1	PFIZER HEALTHCARE IRELAND	IE
Sogilen 2 mg comprimidos	not available	64.409	PFIZER, S.L.	ES
Sogilen 1 mg comprimidos	not available	64.408	PFIZER, S.L.	ES
DOSTINEX 0,5 mg comprimés Cabergoline	not available	BE 159817	PFIZER S.A. (BELGIUM)	BE
DOSTINEX 0,5 mg comprimés Cabergoline	not available	BE 159817	PFIZER S.A. (BELGIUM)	BE
DOSTINEX 0,5 mg tabletten Cabergoline	not available	BE159817	PFIZER S.A. (BELGIUM)	BE
Sostilar 0,5 mg Tabletten Cabergolin	not available	BE168682	PFIZER S.A. (BELGIUM)	BE
SOSTILAR 0,5 mg comprimés Cabergoline	not available	BE168682	PFIZER S.A. (BELGIUM)	BE
SOSTILAR 0,5 mg tabletten Cabergoline	not available	BE168682	PFIZER S.A. (BELGIUM)	BE
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® 0,5 mg Tabletten	not available	32411.00.00	PFIZER PHARMA PFE GMBH	DE
Dostinex 0.5 mg Tablets	not available	PL 00057/0969	PFIZER LIMITED	UK

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 Tablet	not available	PA 822/114/1	PFIZER HEALTHCARE IRELAND	IE
CABASER 1 mg tabletti	not available	11957	PFIZER OY	FI
Dostinex 0,5 mg tabletti	not available	11079	PFIZER OY	FI
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 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
Dostinex 0,5 mg tabletti	not available	11079	PFIZER OY	FI
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
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

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 compresse	not available	028988018	PFIZER ITALIA S.R.L.	IT
Dostinex 0,5 mg comprimidos	not available	2398881	LABORATÓRIOS PFIZER, LDA.	PT
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 compresse	not available	028988032	PFIZER ITALIA S.R.L.	IT
CABASER 1 mg COMPRESSE	not available	031128010	PFIZER ITALIA S.R.L.	IT
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 tableter	not available	7843	PFIZER AS	NO
DOSTINEX 0,5 mg, comprimé	not available	34009 340 427 0 6	PFIZER HOLDING FRANCE	FR
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
DOSTINEX 0,5 mg, comprimé	not available	34009 340 428 7 4	PFIZER HOLDING FRANCE	FR
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 tablettes	not available	04-0309	PFIZER ITALIA S.R.L.	LV
Cabaser, tableter	not available	18072	PFIZER APS	DK
Cabaser, tableter	not available	18071	PFIZER APS	DK
Dostinex® 0,5 mg - Tabletten	not available	1-20438	PFIZER CORPORATION	AT

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			AUSTRIA GESELLSCHAFT M.B.H.	
Dostinex δισκία 0,5 mg	not available	44396/14-9-2009	PFIZER HELLAS, A.E.	GR
DOSTINEX 0,5 mg tablete	not available	UP/I-530-09/12-01/451	PFIZER CROATIA D.O.O.	HR
Dostinex 0,5 mg tabletter	not available	11522	PFIZER AB	SE
Cabaser 1 mg tabletter	not available	12509	PFIZER AB	SE
Cabaser 2 mg tabletter	not available	12510	PFIZER AB	SE
ДОСТИНЕКС 0,5 mg таблетки	not available	20030572	PFIZER EUROPE MA EEIG	BG
DOSTINEX 0,5 mg, comprimate	not available	7619/2006/01	PFIZER EUROPE MA EEIG	RO
DOSTINEX 0,5 mg, comprimate	not available	7619/2006/02	PFIZER EUROPE MA EEIG	RO