



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 October 2022
EMA/862568/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: cabergoline

Procedure no.: PSUSA/00000477/202203



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 töflur.	not available	910091	PFIZER APS	IS
Dostinex 0,5 mg tabletter	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, comprimé	not available	34009 340 428 7 4	PFIZER HOLDING FRANCE	FR
DOSTINEX 0,5 mg, comprimé	not available	34009 302 243 2 8	PFIZER HOLDING FRANCE	FR
DOSTINEX 0,5 mg, comprimé	not available	34009 302 243 4 2	PFIZER HOLDING FRANCE	FR
DOSTINEX 0,5 mg, comprimé	not available	34009 302 243 1 1	PFIZER HOLDING FRANCE	FR
DOSTINEX 0,5 mg Tabletten Cabergolin	not available	BE 159817	PFIZER S.A. (BELGIUM)	BE
ДОСТИНЕКС 0,5 mg таблетки	not available	20030572	PFIZER EUROPE MA EEIG	BG

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, tabletki	not available	4863	PFIZER EUROPE MA EEIG	PL
Dostinex 500 microgram Tablets	not available	PA 822/126/1	PFIZER HEALTHCARE IRELAND	IE
DOSTINEX 0,5 mg compresse	not available	028988020	PFIZER ITALIA S.R.L.	IT
DOSTINEX 0,5 mg compresse	not available	028988018	PFIZER ITALIA S.R.L.	IT
DOSTINEX 0,5 mg compresse	not available	028988032	PFIZER ITALIA S.R.L.	IT
Cabaser 1 mg tabletter	not available	12509	PFIZER AB	SE
Cabaser 2 mg tabletter	not available	12510	PFIZER AB	SE
CABASER 1 mg tablett	not available	11957	PFIZER OY	FI
DOSTINEX 0,5 mg Tabletten Cabergolin	not available	1999095389	PFIZER S.A. (BELGIUM)	LU

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, tabletter	not available	18072	PFIZER APS	DK
Cabaser, tabletter	not available	18071	PFIZER APS	DK
Dostinex 0,5 mg comprimidos.	not available	60.867	PFIZER, S.L.	ES
DOSTINEX 500 mikrogramų tabletės	not available	LT/1/01/1619/001	PFIZER ITALIA S.R.L.	LT
DOSTINEX 500 mikrogramų tabletės	not available	LT/1/01/1619/003	PFIZER ITALIA S.R.L.	LT
DOSTINEX 500 mikrogramų tabletės	not available	LT/1/01/1619/002	PFIZER ITALIA S.R.L.	LT
Dostinex, tabletter	not available	14398	PFIZER APS	DK
CABASER 2 mg COMPRESSE	not available	031128022	PFIZER ITALIA S.R.L.	IT
CABASER 1 mg COMPRESSE	not available	031128010	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 δισκία 0,5 mg	not available	44396/14-9-2009	PFIZER HELLAS, A.E.	GR
Dostinex 0,5 mg tabletter	not available	11522	PFIZER AB	SE
Cabaseril® 1 mg Tabletten	not available	43569.00.00	PFIZER PHARMA GMBH	DE
Cabaseril® 2 mg Tabletten	not available	43569.01.00	PFIZER PHARMA GMBH	DE
Cabaser 1 mg Tablet	not available	PA 822/114/1	PFIZER HEALTHCARE IRELAND	IE
DOSTINEX 0,5 mg tablety	not available	54/277/96-C	PFIZER, SPOL. S R.O.	CZ
Dostinex 0,5 mg comprimate	not available	11765/2019/01	PFIZER EUROPE MA EEIG	RO
Dostinex 0,5 mg comprimate	not available	11765/2019/04	PFIZER EUROPE MA EEIG	RO
Dostinex 0,5 mg comprimate	not available	11765/2019/03	PFIZER EUROPE MA EEIG	RO

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 comprimate	not available	11765/2019/02	PFIZER EUROPE MA EEIG	RO
Sostilar 0,5 mg Tabletten Cabergolin	not available	2001016999	PFIZER S.A. (BELGIUM)	LU
DOSTINEX 0,5 mg tablete	not available	HR-H-951850722	PFIZER CROATIA D.O.O.	HR
Dostinex 0,5 mg comprimidos	not available	2398980	LABORATÓRIOS PFIZER, LDA.	PT
Dostinex 0,5 mg comprimidos	not available	2398881	LABORATÓRIOS PFIZER, LDA.	PT
Dostinex 0,5 mg comprimidos	not available	2399087	LABORATÓRIOS PFIZER, LDA.	PT
Dostinex 0,5 mg comprimidos	not available	5797428	LABORATÓRIOS PFIZER, LDA.	PT
Dostinex 0,5 mg comprimidos	not available	5797410	LABORATÓRIOS PFIZER, LDA.	PT
Cabaseril® 1 mg - Tabletten	not available	1-23067	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT

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
DOSTINEX 0,5 mg tablettes	not available	04-0309	PFIZER ITALIA S.R.L.	LV
ACTUALENE 0,5 mg compresse	not available	033359011	PFIZER ITALIA S.R.L.	IT
ACTUALENE 0,5 mg compresse	not available	033359023	PFIZER ITALIA S.R.L.	IT
ACTUALENE 0,5 mg compresse	not available	033359035	PFIZER ITALIA S.R.L.	IT
Dostinex 0,5 mg tabletti	not available	11079	PFIZER OY	FI
Dostinex® 0,5 mg - Tabletten	not available	1-20438	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Dostinex® 0,5 mg Tabletten	not available	32411.00.00	PFIZER PHARMA GMBH	DE
Dostinex, tabletten 0,5 mg.	not available	RVG 15375	PFIZER B.V.	NL

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Dostinex 500 microgram Tablets	not available	MA505/01401	PFIZER HELLAS, A.E.	MT
Sogilen 2 mg comprimidos	not available	64.409	PFIZER, S.L.	ES
Sogilen 1 mg comprimidos	not available	64.408	PFIZER, S.L.	ES
Sostilar 0,5 mg Tabletten Cabergolin	not available	BE168682	PFIZER S.A. (BELGIUM)	BE