



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 June 2019  
EMA/366211/2019  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: flutamide

Procedure no.: PSUSA/00001453/201810

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<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Flutamide Tablets 250mg	UK/H/0269/001	PL 04569/0338	GENERICS [UK] LIMITED	UK
FLUTAN	not available	4469/2004/01	MEDOCHEMIE LTD.	RO
Flutamid Orion 250 mg tableter	not available	98-1883	ORION CORPORATION	NO
FLUTAMIDA GENERIS 250 mg COMPRIMIDOS	not available	2693083	GENERIS FARMACÊUTICA, S.A.	PT
FLUTAMIDA GENERIS 250 mg COMPRIMIDOS	not available	2693182	GENERIS FARMACÊUTICA, S.A.	PT
Profamid 250 mg tableter	not available	11612	ORION OYJ	FI
Profamid 250 mg tabletti	not available	11612	ORION OYJ	FI
Flutamida cinfa 250 mg comprimidos EFG	not available	62.912	LABORATORIOS CINFA, S.A.	ES
Profamid, tableter	not available	17419	ORION CORPORATION	DK
Flutan 250mg tablets	not available	13410	MEDOCHEMIE LTD.	CY
FLUTAMIDE EG 250 mg, comprimé	not available	NL25342	EG LABO LABORATOIRES EUROGENERICS	FR
Prostacur 250 mg comprimidos	not available	59593	MYLAN PHARMACEUTICALS S.L.	ES
Apo-Flutam, 250 mg, tabletki powlekane	not available	9416	APOTEX EUROPE B.V.	PL
PROSTANDRIL 250 mg tablete	not available	UP/I-530-09/13-02/451	PLIVA HRVATSKA D.O.O.	HR
FLUTASIN 250 MG	not available	44/0147/04-S	ACTAVIS GROUP PTC EHF.	SK
Flutasin 250 mg comprimate	not available	9819/2017/01	ACTAVIS SRL	RO
Flutasin 250 mg comprimate	not available	9819/2017/02	ACTAVIS SRL	RO
ФЛУТАСИН 250 mg таблетки	not available	20011259	ACTAVIS EAD	BG
Flutamide 250 mg Tablets	not available	PL 06464/1799	WAYMADE PLC	UK
Flutamid Stada 250 mg, tableter	SE/H/0166/001	13685	STADA ARZNEIMITTEL AG	SE

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Flutamide EG 250 mg tablet	SE/H/0166/001	BE 216745	EUROGENERICS N.V./S.A.	BE
FLUTAMIDE EG 250 mg Comprese	SE/H/0166/001	034707012	EG SPA	IT
Flutamide EG 250 mg Tabletten	SE/H/0166/001	BE 216745	EUROGENERICS N.V./S.A.	BE
Flutamide EG 250 mg comprimé	SE/H/0166/001	BE 216745	EUROGENERICS N.V./S.A.	BE
FLUTAMIDE EG 250 mg Comprese	SE/H/0166/001	034707024	EG SPA	IT
Flutamide EG 250 mg comprimé	SE/H/0166/001	2002070019	EUROGENERICS N.V./S.A.	LU
FLUTAMIDE MYLAN 250 mg, comprimé	not available	NL24403	MYLAN S.A.S	FR
FLUTAMIDE BIOGARAN 250 mg, comprimé	not available	3400935342805	BIOGARAN	FR
FLUTAMIDE BIOGARAN 250 mg, comprimé	not available	3400935342744	BIOGARAN	FR
Prosneo 250 mg Comprimidos	not available	2822195	FARMOZ - SOCIEDADE TÉCNICO MEDICINAL, S.A.	PT
Prosneo 250 mg Comprimidos	not available	2822294	FARMOZ - SOCIEDADE TÉCNICO MEDICINAL, S.A.	PT
Grisetin 250 mg comprimidos recubiertos con película	not available	59.594	FAES FARMA, S.A.	ES
Flutamid AL 250	not available	42660.00.00	ALIUD PHARMA GMBH	DE
FLUTA-cell® 250 mg Tabletten	not available	39839.00.00	STADAPHARM GMBH	DE
FLUTAMIDE CRISTERS 250 mg, comprimé	not available	34009 356 113 0 7	CRISTERS	FR
FLUTAMIDE CRISTERS 250 mg, comprimé	not available	34009 356 114 7 5	CRISTERS	FR
APO-FLUTAMIDE Potahované	not available	44/018/01-C	APOTEX EUROPE B.V.	CZ

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tablety				
Flutan 250 mg tabletes	not available	98-0042	MEDOCHEMIE LTD.	LV
Flutamid EGIS, 250 mg, tabletki	not available	R/1392	EGIS PHARMACEUTICALS PLC	PL
FLUTAMIDE HEXAL 250 mg compresse	not available	033929 011	SANDOZ S.P.A.	IT