



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 June 2024
EMA/73511/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): flutamide

Procedure No. PSUSA/00001453/202310



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
Flutamide 250mg Tablets	not available	PL 28444/0207	ACTIVASE PHARMACEUTICALS LIMITED	XI
Flutamid AL 250	not available	42660.00.00	ALIUD PHARMA GMBH	DE
FLUTAMIDE EG 250 mg Compresse	SE/H/0166/001	034707012	EG S.P.A.	IT
FLUTAMIDE EG 250 mg Compresse	SE/H/0166/001	034707024	EG S.P.A.	IT
Flutamid EGIS, 250 mg, tabletki	not available	R/1392	EGIS PHARMACEUTICALS PLC	PL
Flutamide EG 250 mg tablet	SE/H/0166/001	BE216745	EUROGENERICS N.V./S.A.	BE
Flutamide EG 250 mg Tabletten	SE/H/0166/001	BE216745	EUROGENERICS N.V./S.A.	BE
Flutamide EG 250 mg comprimé	SE/H/0166/001	BE216745	EUROGENERICS N.V./S.A.	BE
Flutamide EG 250 mg comprimé	SE/H/0166/001	2002070019	EUROGENERICS N.V./S.A.	LU
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
Flutamide 250 mg Tablets	not available	PL 04569/0338	GENERIC [UK] LIMITED	XI
ROSINIOL®	not available	72943/09	IOULIA AND IRENE TSETI PHARMACEUTICAL LABORATORIES S.A.	GR
flutamida cinfa 250 mg comprimidos EFG	not available	62.912	LABORATORIOS CINFA, S.A.	ES
Flutan 250mg tablets	not available	13410	MEDOCHÉMIE LTD.	CY
Flutan 250 mg tabletes	not available	98-0042	MEDOCHÉMIE LTD.	LV
Flutan 250 mg comprimate	not available	11473/2019/01	MEDOCHÉMIE LTD.	RO
Prostacur 250 mg comprimidos	not available	59593	MYLAN PHARMACEUTICALS S.L.	ES

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Profamid 250 mg tabletter	not available	11612	ORION CORPORATION	FI
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FLUTAMIDE HEXAL 250 mg compresse	not available	033929 011	SANDOZ S.P.A.	IT
Flutamid Stada 250 mg, tabletter	SE/H/0166/001	13685	STADA ARZNEIMITTEL AG	SE
FLUTA-cell® 250 mg Tabletten	not available	39839.00.00	STADAPHARM GMBH	DE
Flutamide 250 mg Tablets	not available	PL 06464/1799	WAYMADE PLC	XI