



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 June 2016
EMA/418272/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: letrozole

Procedure no.: PSUSA/00001842/201510



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
Letrozol - 1 A Pharma 2,5 mg film-coated tablets	NOT APPLICABLE	AA939/06301	1 A PHARMA GMBH	MT
Femara 2,5 mg comprimate filmate	FR/H/0110/001	5026/2012/03	NOVARTIS PHARMA GMBH	RO
Femara 2,5 mg comprimate filmate	FR/H/0110/001	5026/2012/04	NOVARTIS PHARMA GMBH	RO
Femara 2,5 mg comprimate filmate	FR/H/0110/001	5026/2012/05	NOVARTIS PHARMA GMBH	RO
Femara 2,5 mg plêvele dengtos tabletès	FR/H/0110/001	LT/1/98/0128/002	NOVARTIS FINLAND OY	LT
Femara 2,5 mg plêvele dengtos tabletès	FR/H/0110/001	LT/1/98/0128/003	NOVARTIS FINLAND OY	LT
Femara 2,5 mg plêvele dengtos tabletès	FR/H/0110/001	LT/1/98/0128/004	NOVARTIS FINLAND OY	LT
Femara 2,5 mg plêvele dengtos tabletès	FR/H/0110/001	LT/1/98/0128/005	NOVARTIS FINLAND OY	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
Femara 2,5 mg comprimé pelliculé	FR/H/0110/001	2008079869	NOVARTIS PHARMA N.V.	LU
FEMARA 2,5 mg Filmtabletten	FR/H/0110/001	2008079869	NOVARTIS PHARMA N.V.	LU
FEMARA 2,5 mg Filmtabletten	FR/H/0110/001	BE182926	NOVARTIS PHARMA N.V.	BE
Femara 2.5 mg filmom obložene tablete	FR/H/0110/001	HR-H-020668711-02	NOVARTIS HRVATSKA D.O.O.	HR
Femara 2.5 mg filmom obložene tablete	FR/H/0110/001	HR-H-020668711-03	NOVARTIS HRVATSKA D.O.O.	HR
Femara 2.5 mg filmom obložene tablete	FR/H/0110/001	HR-H-020668711-04	NOVARTIS HRVATSKA D.O.O.	HR
Femara 2.5 mg filmom obložene tablete	FR/H/0110/001	HR-H-020668711-05	NOVARTIS HRVATSKA D.O.O.	HR
Femar 2,5 mg filmuhúðuð tafla	FR/H/0110/001	960198	NOVARTIS HEALTHCARE A/S	IS

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
FEMARA 2,5 mg compresse rivestite con film	FR/H/0110/001	033242037	NOVARTIS EUROPHARM LIMITED	IT
FEMARA 2,5 mg compresse rivestite con film	FR/H/0110/001	033242049	NOVARTIS EUROPHARM LIMITED	IT
FEMARA 2,5 mg compresse rivestite con film	FR/H/0110/001	033242052	NOVARTIS EUROPHARM LIMITED	IT
Femara 2,5 mg apvalkotās tabletes	FR/H/0110/001	98-0087	NOVARTIS FINLAND OY	LV
FEMARA®2,5 MG ΔΙΣΚΙΑ ΕΠΙΚΑΛΥΜΜΕΝΑ ΜΕ ΛΕΠΤΟ ΥΜΕΝΙΟ	FR/H/0110/001	233170101	NOVARTIS (HELLAS) S.A.C.I.	GR
FEMARA®2,5 MG ΔΙΣΚΙΑ ΕΠΙΚΑΛΥΜΜΕΝΑ ΜΕ ΛΕΠΤΟ ΥΜΕΝΙΟ	FR/H/0110/001	233170102	NOVARTIS (HELLAS) S.A.C.I.	GR
LOXIFAN 2,5 mg comprimidos recubiertos recubiertos con película	not available	62.079	LABORATORIOS PADRÓ, S.A.	ES
Femara 2,5 mg comprimidos revestidos por película	FR/H/0110/001	2499986	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	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
Femara 2,5 mg comprimidos revestidos por película	FR/H/0110/001	2500080	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Femara 2,5 mg comprimidos revestidos por película	FR/H/0110/001	5123583	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Femara 2,5 mg plévele dengtos tabletès	FR/H/0110/001	LT/1/98/0128/001	NOVARTIS FINLAND OY	LT
FEMARA 2.5 mg comprimidos recubiertos con película	FR/H/0110/001	61628	NOVARTIS FARMACÉUTICA S.A.	ES
Femara 2,5 mg	FR/H/0110/001	38895.00.00	NOVARTIS PHARMA GMBH	DE
Femara 2,5 mg	FR/H/0110/001	0135/08079869	NOVARTIS PHARMA GMBH	LU
Femara 2,5 mg filmtabletta	FR/H/0110/001	OGYI-T-5712/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Femara, filmomhulde tabletten 2,5 mg	FR/H/0110/001	RVG 20755	NOVARTIS PHARMA B.V.	NL

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
Femara 2,5 mg filmdragerad tablett	FR/H/0110/001	13261	NOVARTIS SVERIGE AB	SE
FEMARA® 2.5MG, FILM COATED TABLETS	FR/H/0110/001	088/01101	NOVARTIS PHARMACEUTICALS UK LIMITED	MT
Femara 2,5 mg - Filmtabletten	FR/H/0110/001	1-21781	NOVARTIS PHARMA GMBH	AT
Femara 2,5 mg comprimés pelliculés	FR/H/0110/001	BE182926	NOVARTIS PHARMA N.V.	BE
Femara 2,5 mg filmomhulde tabletten	FR/H/0110/001	BE182926	NOVARTIS PHARMA N.V.	BE
FEMARA, 2.5 mg, comprimé pelliculé	FR/H/0110/001	3400934147425	NOVARTIS PHARMA S.A.S.	FR
Femara 2.5 mg film coated tablets	FR/H/0110/001	PA 13/80/1	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Femara 2.5mg Tablets	FR/H/0110/001	PL 00101/0493	NOVARTIS PHARMACEUTICALS UK 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
FEMARA® 2,5 MG, ΕΠΙΚΑΛΥΜΜΕΝΟ ΜΕ ΛΕΠΤΟ ΥΜΕΝΙΟ ΔΙΣΚΊΟ	FR/H/0110/001	18468	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
Femara 2,5 mg	FR/H/0110/001	44/0029/99-S	NOVARTIS, S.R.O.	SK
Femar	FR/H/0110/001	18420	NOVARTIS HEALTHCARE A/S	DK
FEMAR 2,5 mg tabletter, filmdrasjerte	FR/H/0110/001	96-1423	NOVARTIS NORGE AS	NO
Femar 2,5 mg tabletti, kalvopäällysteinen	FR/H/0110/001	12452	NOVARTIS FINLAND OY	FI
Femar 2,5 mg tabletti, kalvopäällysteinen	FR/H/0110/001	12452	NOVARTIS FINLAND OY	FI
Femara, 2,5 mg õhukese polümeerikattega tablett	FR/H/0110/001	246799	NOVARTIS FINLAND OY	EE
Femara 2,5 mg comprimate filmate	FR/H/0110/001	5026/2012/01	NOVARTIS PHARMA GMBH	RO
Femara 2,5 mg comprimate filmate	FR/H/0110/001	5026/2012/02	NOVARTIS PHARMA GMBH	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
Femara 2,5 mg potahované tablety	FR/H/0110/001	44/283/99-C	NOVARTIS, S.R.O.	CZ
Femara 2,5 mg filmsko obložene tablete	FR/H/0110/001	5363-I-1850/12	NOVARTIS PHARMA GMBH	SI
FEMARA 2,5 mg compresse rivestite con film	FR/H/0110/001	033242013	NOVARTIS EUROPHARM LIMITED	IT
FEMARA 2,5 mg compresse rivestite con film	FR/H/0110/001	033242025	NOVARTIS EUROPHARM LIMITED	IT
Femara 2,5 mg film coated tablets / Фемара 2,5 mg филмирани таблетки	FR/H/0110/001	20020268	NOVARTIS PHARMA GMBH	BG
Femara 2.5 mg filmom obložene tablete	FR/H/0110/001	HR-H-020668711-01	NOVARTIS HRVATSKA D.O.O.	HR
Femara 2,5 mg filmtabletta	FR/H/0110/001	OGYI-T-5712/02	NOVARTIS HUNGÁRIA KFT. PHARMA	HU