



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 October 2017
EMA/716500/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): bicalutamide

Procedure No.: PSUSA/00000407/201702



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
Biluron 150 mg, filmomhulde tabletten	NL/H/2299/002	RVG 102251	GENTHON BV	NL
Bicalutamide 50 mg Film-coated Tablets	-	PL 40378/0134	TORRENT PHARMA LTD.	UK
Bicalutamide 150 mg Film-coated Tablets	-	PL 40378/0135	TORRENT PHARMA LTD.	UK
Bicalutamide 150 PCH, filmomhulde tabletten 150 mg	CZ/H/0133/002	RVG 34468	PHARMACHEMIE B.V	NL
Casodex 150 mg filmom obložene tablete	not available	UP/I-530-09/12-02/87	ASTRAZENECA D.O.O.	HR
Casodex 50 mg filmom obložene tablete	not available	HR-H-959901547	ASTRAZENECA D.O.O.	HR
Casodex 150 mg comprimidos recubiertos con película	not available	71927	ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	ES
Casodex 150 mg filmdragerade tabletter.	not available	14025	ASTRAZENECA AB	SE
Casodex® 150 mg Filmtabletten	not available	70945.00.00	ASTRAZENECA GMBH	DE
Casodex, filmovertrukne tabletter	not available	31525	ASTRAZENECA A/S	DK
Casodex, 150 mg õhukese polümeerikattega tabletid	not available	348001	ASTRAZENECA UK LIMITED	EE
Casodex® 50 mg tabletti, kalvopäällysteinen	not available	11863	ASTRAZENECA OY	FI
Casodex 150 mg plėvele dengtos tabletės	not available	LT/0/97/1333/002	ASTRAZENECA UK LIMITED	LT
CASODEX 150, comprimés pelliculés	not available	BE233143	NV ASTRAZENECA SA	BE
CASODEX 150, filmomhulde tabletten	not available	BE233143	NV ASTRAZENECA SA	BE
Casodex®-50, filmomhulde tablet 50 mg	not available	RVG 18356	ASTRAZENECA BV	NL
CASODEX 150 mg compresse rivestite con film	not available	301113020	ASTRAZENECA S.P.A.	IT
Casodex® 150 mg tabletti, kalvopäällysteinen	not available	15571	ASTRAZENECA OY	FI
Casodex 150 mg, επικαλυμμένα με λεπτό υμένιο δισκία	not available	19272	ASTRAZENECA UK LIMITED	CY
CASODEX 50, filmomhulde	not available	BE179033	NV ASTRAZENECA SA	BE

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tabletten				
CASODEX 50, comprimés pelliculés	not available	BE179033	NV ASTRAZENECA SA	BE
Казодекс 50 mg филмирани таблетки	not available	9600153	ASTRAZENECA UK LIMITED	BG
Casodex 50 mg - Filmtabletten	not available	1-21748	ASTRAZENECA OSTERREICH GMBH	AT
CASODEX, 50 mg õhukese polümeerikattega tabletid	not available	162497	ASTRAZENECA UK LIMITED	EE
Casodex® 50 mg Film-coated Tablets	not available	PA 970/4/1	ASTRAZENECA UK LIMITED	IE
Casodex 50 mg comprimidos revestidos por película	not available	2801280	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Casodex 50 mg comprimidos revestidos por película	not available	2801181	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
CASODEX 50 mg, comprimé enrobé	not available	NL 20612	ASTRAZENECA S.A.S.	FR
Casodex, 50 mg, film-coated tablet	not available	R/7333	ASTRAZENECA UK LIMITED	PL
CASODEX 50 mg compresse rivestite con film	not available	031113018	ASTRAZENECA S.P.A.	IT
Casodex 50 mg Film-coated Tablets	not available	PL17901/0005	ASTRAZENECA UK LIMITED	UK
Casodex 50 mg comprimidos recubiertos con película	not available	61.055	ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	ES
Casodex 50 mg filmdragerade tabletter	not available	12317	ASTRAZENECA AB	SE
Casodex 50 mg plėvele dengtos tabletės	not available	LT/0/97/1333/001	ASTRAZENECA UK LIMITED	LT
Casodex 150 mg tablett, filmdrasjert	not available	97-3945	ASTRAZENECA AS	NO
Casodex 50 mg tablett, filmdrasjert	not available	94-2575	ASTRAZENECA AS	NO
Casodex 50 mg filmsko obložene tablete	not available	H/96/00346/001	ASTRAZENECA UK LIMITED	SI
Casodex 150 mg filmsko obložene tablete	not available	H/96/00346/002	ASTRAZENECA UK LIMITED	SI
Casodex 50 mg, δισκία	not available	18331	ASTRAZENECA UK LIMITED	CY

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επικαλυμμένα με λεπτό υμένιο				
Casodex® 50 mg Filmtabletten	not available	34057.00.00	ASTRAZENECA GMBH	DE
Casodex 50 mg, δισκία επικαλυμμένα με λεπτό υμένιο	not available	8492/6-2-2007	ASTRAZENECA S.A	GR
CASODEX 150, 150 mg, comprimés pelliculés	not available	2008019644	ASTRAZENECA S.A. / N.V.	LU
CASODEX 50, 50 mg, comprimés pelliculés	not available	2008019643	ASTRAZENECA S.A. / N.V.	LU
CASODEX 50 mg, comprimé filmaté	not available	8524/2016/01	ASTRAZENECA UK LIMITED	RO
Casodex 150 mg comprimé filmaté	not available	3387/2011/01	ASTRAZENECA UK LIMITED	RO
Bicalutamide Aurobindo 150 mg, filmomhulde tabletten	not available	RVG 116494	AUROBINDO PHARMA B.V.	NL
Probic 50 mg comprimidos recubiertos con película	not available	68.083	LABORATORIOS Q PHARMA S.L.	ES
Bicalutamide Aurobindo 150 mg, filmomhulde tabletten	not available	RVG 116494	AUROBINDO PHARMA B.V.	NL
Casodex® 150 mg film-coated tablets	UK/H/0364/001	PL17901/0006	ASTRAZENECA UK LIMITED	UK
Casodex 150 mg comprimidos revestidos por película	UK/H/0364/001	3424488	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Casodex 150 mg comprimidos revestidos por película	UK/H/0364/001	3425188	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Casodex 150 mg comprimidos revestidos por película	UK/H/0364/001	3424884	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Casodex 150 mg comprimidos revestidos por película	UK/H/0364/001	3425287	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Casodex 150 mg comprimidos revestidos por película	UK/H/0364/001	3424785	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Casodex 150 mg comprimidos revestidos por película	UK/H/0364/001	3425485	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Casodex 150 mg comprimidos revestidos por película	UK/H/0364/001	3425782	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Casodex 150 mg comprimidos revestidos por película	UK/H/0364/001	3424587	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Casodex 150 mg comprimidos	UK/H/0364/001	3425584	ASTRAZENECA PRODUTOS	PT

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revestidos por película			FARMACEUTICOS LDA.	
Casodex 150 mg comprimidos revestidos por película	UK/H/0364/001	3425089	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Casodex 150 mg comprimidos revestidos por película	UK/H/0364/001	3425386	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Casodex 150 mg comprimidos revestidos por película	UK/H/0364/001	3424686	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Casodex 150 mg comprimidos revestidos por película	UK/H/0364/001	3424983	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Casodex 150 mg comprimidos revestidos por película	UK/H/0364/001	3425683	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Casodex 150 mg – Filmdabletten	UK/H/0364/001	1-23884	ASTRAZENECA OSTERREICH GMBH	AT
Casodex 150 mg, επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0364/001	29121/19-04-2013	ASTRAZENECA S.A	GR