



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 October 2023
EMA/299590/2023
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: bicalutamide

Procedure no.: PSUSA/00000407/202302

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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
Casodex 50 mg - Filmtabletten	not available	1-21748	LABORATOIRES JUVISE PHARMACEUTICALS	AT
Casodex 150 mg – Filmtabletten	not available	1-23884	LABORATOIRES JUVISE PHARMACEUTICALS	AT
CASODEX 50, 50 mg, comprimés pelliculés	not available	BE179033	LABORATOIRES JUVISE PHARMACEUTICALS	BE
CASODEX 150, 150 mg, comprimés pelliculés	not available	BE233143	LABORATOIRES JUVISE PHARMACEUTICALS	BE
CASODEX 50, 50 mg, filmomhulde tabletten	not available	BE179033	LABORATOIRES JUVISE PHARMACEUTICALS	BE
CASODEX 150, 150 mg, filmomhulde tabletten	not available	BE233143	LABORATOIRES JUVISE PHARMACEUTICALS	BE
CASODEX 50, 50 mg Filmtabletten	not available	BE179033	LABORATOIRES JUVISE PHARMACEUTICALS	BE
CASODEX 150, 150 mg Filmtabletten	not available	BE233143	LABORATOIRES JUVISE PHARMACEUTICALS	BE
Casodex 50 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	18331	LABORATOIRES JUVISE PHARMACEUTICALS	CY

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
Casodex® 50 mg Filmtabletten	not available	34057.00.00	LABORATOIRES JUVISE PHARMACEUTICALS	DE
Casodex® 150 mg Filmtabletten	not available	70945.00.00	LABORATOIRES JUVISE PHARMACEUTICALS	DE
Casodex® 50 mg Filmtabletten	not available	34057.00.00	LABORATOIRES JUVISE PHARMACEUTICALS	DE
Casodex® 150 mg Filmtabletten	not available	70945.00.00	LABORATOIRES JUVISE PHARMACEUTICALS	DE
Casodex, filmoverttrukne tabletter	not available	31525	LABORATOIRES JUVISE PHARMACEUTICALS	DK
Casodex, 50 mg õhukese polümeerikattega tabletid	not available	162497	LABORATOIRES JUVISE PHARMACEUTICALS	EE
Casodex, 150 mg õhukese polümeerikattega tabletid	not available	348001	LABORATOIRES JUVISE PHARMACEUTICALS	EE
Casodex 50 mg comprimidos recubiertos con película	not available	61.055	LABORATOIRES JUVISE PHARMACEUTICALS	ES
Casodex 150 mg comprimidos recubiertos con película	not available	71.927	LABORATOIRES JUVISE PHARMACEUTICALS	ES

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
Pencial 50 mg comprimidos recubiertos con película	not available	68161	BIOWISE PHARMACEUTICALS, S.L.	ES
Probic 50 mg comprimidos recubiertos con película	not available	68.083	LABORATORIOS Q PHARMA S.L.	ES
Casodex® 150 mg tabletti, kalvopäällysteinen.	not available	15571	LABORATOIRES JUVISE PHARMACEUTICALS	FI
Casodex® 50 mg tabletti, kalvopäällysteinen	not available	11863	LABORATOIRES JUVISE PHARMACEUTICALS	FI
Casodex® 150 mg filmdragerad tablett.	not available	15571	LABORATOIRES JUVISE PHARMACEUTICALS	FI
Casodex® 150 mg filmdragerad tablett.	not available	15571	LABORATOIRES JUVISE PHARMACEUTICALS	FI
Casodex® 50 mg filmdragerad tablett	not available	11863	LABORATOIRES JUVISE PHARMACEUTICALS	FI
Casodex® 50 mg filmdragerad tablett	not available	11863	LABORATOIRES JUVISE PHARMACEUTICALS	FI
Casodex® 150 mg tabletti, kalvopäällysteinen.	not available	15571	LABORATOIRES JUVISE PHARMACEUTICALS	FI

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
Casodex® 50 mg tabletti, kalvopäällysteinen	not available	11863	LABORATOIRES JUVISE PHARMACEUTICALS	FI
CASODEX 50 mg, comprimé enrobé	not available	34009 339 163 3 6	LABORATOIRES JUVISE PHARMACEUTICALS	FR
CASODEX 50 mg, comprimé enrobé	not available	34009 339 162 7 5	LABORATOIRES JUVISE PHARMACEUTICALS	FR
CASODEX 50 mg, comprimé enrobé	not available	34009 387 106 6 3	LABORATOIRES JUVISE PHARMACEUTICALS	FR
CASODEX 50 mg, comprimé enrobé	not available	34009 387 107 2 4	LABORATOIRES JUVISE PHARMACEUTICALS	FR
CASODEX 50 mg, comprimé enrobé	not available	34009 387 109 5 3	LABORATOIRES JUVISE PHARMACEUTICALS	FR
CASODEX 50 mg, comprimé enrobé	not available	34009 559 183 3 2	LABORATOIRES JUVISE PHARMACEUTICALS	FR
Casodex 150 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	99460/21-10-2021	LABORATOIRES JUVISE PHARMACEUTICALS	GR
Casodex 150 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	99460/21-10-2021	LABORATOIRES JUVISE PHARMACEUTICALS	GR

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
Casodex 150 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	99460/21-10-2021	LABORATOIRES JUVISE PHARMACEUTICALS	GR
Casodex 150 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	99460/21-10-2021	LABORATOIRES JUVISE PHARMACEUTICALS	GR
Casodex 150 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	99460/21-10-2021	LABORATOIRES JUVISE PHARMACEUTICALS	GR
Casodex 150 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	99460/21-10-2021	LABORATOIRES JUVISE PHARMACEUTICALS	GR
Casodex 50 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	63471/21-10-2021	LABORATOIRES JUVISE PHARMACEUTICALS	GR
Casodex 50 mg filmom obložene tablete	not available	HR-H-959901547	LABORATOIRES JUVISE PHARMACEUTICALS	HR
Casodex 150 mg filmom obložene tablete	not available	HR-H-423625979	LABORATOIRES JUVISE PHARMACEUTICALS	HR
Casodex® 50 mg Film-coated Tablets	not available	PA 23154/002/001	LABORATOIRES JUVISE PHARMACEUTICALS	IE
CASODEX 50 mg compresse rivestite con film	not available	031113018	LABORATOIRES JUVISE PHARMACEUTICALS	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
CASODEX 150 mg compresse rivestite con film	not available	031113020	LABORATOIRES JUVISE PHARMACEUTICALS	IT
CASODEX 50, 50 mg, comprimés pelliculés	not available	2008019643	LABORATOIRES JUVISE PHARMACEUTICALS	LU
CASODEX 150, 150 mg, comprimés pelliculés	not available	2008019644	LABORATOIRES JUVISE PHARMACEUTICALS	LU
CASODEX 50, 50 mg Filmtabletten	not available	2008019643	LABORATOIRES JUVISE PHARMACEUTICALS	LU
CASODEX 150, 150 mg Filmtabletten	not available	2008019644	LABORATOIRES JUVISE PHARMACEUTICALS	LU
Bicalutamide Aurobindo 150 mg, filmomhulde tabletten	not available	RVG 116494	AUROBINDO PHARMA B.V.	NL
Casodex-50, filmomhulde tabletten 50 mg	not available	RVG 18356	LABORATOIRES JUVISE PHARMACEUTICALS	NL
Casodex-50, filmomhulde tabletten 50 mg	not available	RVG 18356	LABORATOIRES JUVISE PHARMACEUTICALS	NL
Bicalutamide Synthron 150 mg, filmomhulde tabletten	not available	RVG 118073	SYNTHON BV	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
Biluron 150 mg, filmomhulde tabletten	NL/H/2299/002	RVG 102551	GENTHON BV	NL
Bicalutamide 150 PCH, filmomhulde tabletten 150 mg	CZ/H/0133/002	RVG 34468	PHARMACHEMIE B.V	NL
Bicalutamide Synthon 150 mg, filmomhulde tabletten	not available	RVG 118073	SYNTHON BV	NL
Casodex 50 mg tablett, filmdrasjert	not available	94-2575	LABORATOIRES JUVISE PHARMACEUTICALS	NO
Casodex 50 mg tablett, filmdrasjert	not available	94-2575	LABORATOIRES JUVISE PHARMACEUTICALS	NO
Casodex 150 mg tablett, filmdrasjert	not available	97-3945	LABORATOIRES JUVISE PHARMACEUTICALS	NO
Casodex 150 mg tablett, filmdrasjert	not available	97-3945	LABORATOIRES JUVISE PHARMACEUTICALS	NO
Casodex 150 mg tablett, filmdrasjert	not available	97-3945	LABORATOIRES JUVISE PHARMACEUTICALS	NO
Casodex 50 mg tablett, filmdrasjert	not available	94-2575	LABORATOIRES JUVISE PHARMACEUTICALS	NO

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
Casodex 150 mg comprimate filmate	not available	3387/2011/01	LABORATOIRES JUVISE PHARMACEUTICALS	RO
Casodex 50 mg comprimate filmate	not available	8524/2016/01	LABORATOIRES JUVISE PHARMACEUTICALS	RO
Casodex 150 mg filmdragerade tabletter.	not available	14025	LABORATOIRES JUVISE PHARMACEUTICALS	SE
Casodex 50 mg filmdragerade tabletter.	not available	12317	LABORATOIRES JUVISE PHARMACEUTICALS	SE
Casodex 150 mg filmdragerade tabletter.	not available	14025	LABORATOIRES JUVISE PHARMACEUTICALS	SE
Casodex 150 mg filmdragerade tabletter.	not available	14025	LABORATOIRES JUVISE PHARMACEUTICALS	SE
Casodex 150 mg filmdragerade tabletter.	not available	14025	LABORATOIRES JUVISE PHARMACEUTICALS	SE
Casodex 150 mg filmdragerade tabletter.	not available	14025	LABORATOIRES JUVISE PHARMACEUTICALS	SE
Casodex 50 mg filmdragerade tabletter.	not available	12317	LABORATOIRES JUVISE PHARMACEUTICALS	SE

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
Casodex 50 mg filmdragerade tabletter.	not available	12317	LABORATOIRES JUVISE PHARMACEUTICALS	SE
Casodex 50 mg filmdragerade tabletter.	not available	12317	LABORATOIRES JUVISE PHARMACEUTICALS	SE
Casodex 50 mg filmdragerade tabletter.	not available	12317	LABORATOIRES JUVISE PHARMACEUTICALS	SE
Casodex 50 mg filmsko obložene tablete	not available	H/96/00346/001	LABORATOIRES JUVISE PHARMACEUTICALS	SI
Casodex 150 mg filmsko obložene tablete	not available	H/96/00346/002	LABORATOIRES JUVISE PHARMACEUTICALS	SI
Bicalutamide 50mg Film-coated Tablets	not available	PL 36687/0262	TORRENT PHARMA (UK) LTD.	XI
Bicalutamide 150 mg Film-coated Tablets	not available	PL 36687/0263	TORRENT PHARMA (UK) LTD.	XI