



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 July 2018
EMA/537178/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): dutasteride, dutasteride / tamsulosin

Procedure No.: PSUSA/00010506/201711



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
Duagen 0,5 mg capsule molli	SE/H/0305/001	035896012	GLAXOSMITHKLINE S.P.A.	IT
Duagen 0,5 mg capsule molli	SE/H/0305/001	035896024	GLAXOSMITHKLINE S.P.A.	IT
Duagen 0,5 mg cápsulas moles	SE/H/0305/001	4280988	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
Duagen 0,5 mg cápsulas moles	SE/H/0305/001	4280889	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
Duagen 0,5 mg cápsulas moles	SE/H/0305/001	4389581	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
Duagen 0,5 mg cápsulas moles	SE/H/0305/001	5758081	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
Duagen 0,5 mg mjuka kapslar	SE/H/0305/001	17872	GLAXO GROUP LIMITED	SE
Avodart 0,5 mg lágy kapszula	SE/H/0304/001	OGYI-T-9079/01	GLAXOSMITHKLINE KFT.	HU
Avodart 0,5 mg lágy kapszula	SE/H/0304/001	OGYI-T-9079/02	GLAXOSMITHKLINE KFT.	HU
Avodart 0,5 mg minkštosios kapsulės	SE/H/0304/001	LT/1/06/0475/001	GLAXO GROUP LIMITED	LT
Avodart 0,5 mg minkštosios kapsulės	SE/H/0304/001	LT/1/06/0475/002	GLAXO GROUP LIMITED	LT
Avodart 0,5 mg minkštosios kapsulės	SE/H/0304/001	LT/1/06/0475/003	GLAXO GROUP LIMITED	LT
Avodart 0,5 mg minkštosios kapsulės	SE/H/0304/001	LT/1/06/0475/005	GLAXO GROUP LIMITED	LT
Avodart 0,5 mg minkštosios kapsulės	SE/H/0304/001	LT/1/06/0475/004	GLAXO GROUP LIMITED	LT
Avodart 0,5 mg lágy kapszula	SE/H/0304/001	OGYI-T-9079/03	GLAXOSMITHKLINE KFT.	HU
Avodart 0,5 mg lágy kapszula	SE/H/0304/001	OGYI-T-9079/04	GLAXOSMITHKLINE KFT.	HU
Avodart 0,5 mg mjuka kapslar	SE/H/0304/001	19814	GLAXOSMITHKLINE OY	FI
Avodart 0,5 mg zachte capsules	SE/H/0304/001	BE250381	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Avodart 0,5 mg Weichkapseln Dutasterid	SE/H/0304/001	BE250381	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE

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Avodart 0,5 mg capsule moi	SE/H/0304/001	7029/2014/01	GLAXOSMITHKLINE (GSK) S.R.L.	RO
Avodart 0,5 mg capsule moi	SE/H/0304/001	7029/2014/02	GLAXOSMITHKLINE (GSK) S.R.L.	RO
Avodart 0,5 mg capsule moi	SE/H/0304/001	7029/2014/03	GLAXOSMITHKLINE (GSK) S.R.L.	RO
Avodart 0,5 mg capsule moi	SE/H/0304/001	7029/2014/04	GLAXOSMITHKLINE (GSK) S.R.L.	RO
Avodart 0,5 mg capsule moi	SE/H/0304/001	7029/2014/05	GLAXOSMITHKLINE (GSK) S.R.L.	RO
Avodart 0,5 mg Weichkapseln Dutasterid	SE/H/0304/001	2008 01 9608	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Avodart 0,5 mg mehke kapsule	SE/H/0304/001	H/04/00243/003	GLAXOSMITHKLINE D.O.O.	SI
Avodart 0,5 mg mehke kapsule	SE/H/0304/001	H/04/00243/004	GLAXOSMITHKLINE D.O.O.	SI
Avodart 0,5 mg mehke kapsule	SE/H/0304/001	H/04/00243/005	GLAXOSMITHKLINE D.O.O.	SI
Avodart 0,5 mg Weichkapseln	SE/H/0304/001	1-24844	GLAXOSMITHKLINE PHARMA GMBH.	AT
Avodart 0,5 mg capsules molles	SE/H/0304/001	BE250381	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Аводарт 0,5 mg меки капсули	SE/H/0304/001	20040103	GLAXOSMITHKLINE EOOD	BG
Avodart 0,5 mg μαλακά καψάκια	SE/H/0304/001	19719	GLAXO GROUP LIMITED	CY
Avodart 0,5 mg měkké tobolky	SE/H/0304/001	87/287/03-C	GLAXO GROUP LIMITED	CZ
Avodart	SE/H/0304/001	34267	GLAXOSMITHKLINE PHARMA A/S	DK
Avodart, 0,5 mg pehmekapslid	SE/H/0304/001	421703	GLAXOSMITHKLINE EESTI OÜ	EE
Avodart 0,5 mg pehmeät kapselit	SE/H/0304/001	19814	GLAXOSMITHKLINE OY	FI
AVODART 0,5 mg, capsule molle	SE/H/0304/001	NL28131	LABORATOIRE GLAXOSMITHKLINE	FR

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Avodart 0,5 mg Weichkapseln	SE/H/0304/001	55613.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Avodart 0,5 mg mjúk hylki	SE/H/0304/001	IS/1/02/044/01	GLAXOSMITHKLINE PHARMA A/S	IS
Avodart 0.5 mg soft capsules	SE/H/0304/001	PA1077/104/001	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Avodart 0,5 mg mīkstās kapsulas	SE- SE/H/0304/001	04-0410	GLAXO GROUP LIMITED	LV
Avodart 0,5 mg capsules molles	SE/H/0304/001	2008 01 9608	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Avodart 0.5 mg soft capsules	SE/H/0304/001	MA 300/00301	GLAXOSMITHKLINE UK LIMITED	MT
Avodart 0,5 mg zachte capsules	SE/H/0304/001	RVG 28317	GLAXOSMITHKLINE B.V.	NL
Avodart 0,5 mg myke kapsler	SE/H/0304/001	02-1382	GLAXOSMITHKLINE AS	NO
Avodart, 0,5 mg, kapsułki miękkie	SE/H/0304/001	11165	GLAXOSMITHKLINE EXPORT LTD	PL
Avodart 0,5 mg capsule molli	SE/H/0304/001	035895010	GLAXOSMITHKLINE S.P.A.	IT
Avodart 0,5 mg capsule molli	SE/H/0304/001	035895022	GLAXOSMITHKLINE S.P.A.	IT
Avodart 0,5 mg cápsulas moles	SE/H/0304/001	5744289	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Avodart 0,5 mg cápsulas moles	SE/H/0304/001	4351284	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Avodart 0,5 mg cápsulas moles	SE/H/0304/001	4280780	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Avodart 0,5 mg cápsulas moles	SE/H/0304/001	4280681	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Avodart 0,5 mg mäkké kapsuly	SE/H/0304/001	87/0286/04-S	GLAXO GROUP LIMITED	SK
Avodart 0,5 mg mehke kapsule	SE/H/0304/001	H/04/00243/001	GLAXOSMITHKLINE D.O.O.	SI
Avodart 0,5 mg mehke kapsule	SE/H/0304/001	H/04/00243/002	GLAXOSMITHKLINE D.O.O.	SI

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Avidart 0,5 mg cápsulas blandas	SE/H/0304/001	65.178	GLAXOSMITHKLINE, S.A.	ES
Avodart 0,5 mg mjuka kapslar	SE/H/0304/001	17871	GLAXO GROUP LIMITED	SE
Avodart 0,5 mg μαλακά κάψαλα	SE/H/0304/001	2578701	GLAXOSMITHKLINE AEBE	GR
Dutasterid-Tamsulosinhydrochlorid GlaxoSmithKline 0,5 mg/0,4 mg Hartkapseln	DE/H/2252/001	76878.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Jelnu 0,5 mg / 0,4 mg capsule rigide	DE/H/2252/001	039906019	GLAXOSMITHKLINE S.P.A.	IT
Jelnu 0,5 mg / 0,4 mg capsule rigide	DE/H/2252/001	039906021	GLAXOSMITHKLINE S.P.A.	IT
Jelnu 0,5 mg / 0,4 mg capsule rigide	DE/H/2252/001	039906033	GLAXOSMITHKLINE S.P.A.	IT
Juteo 0,5 mg / 0,4 mg cápsulas	DE/H/2252/001	5284955	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
Avodart 0,5 mg Weichkapseln	SE/H/0304/001	1-24844	GLAXOSMITHKLINE PHARMA GMBH.	AT
Avodart 0,5 mg meke kapsule	not available	HR-H-357757654	GLAXOSMITHKLINE D.O.O.	HR
Duodart 0,5 mg/0,4 mg tvrde kapsule	not available	HR-H-979570583	GLAXOSMITHKLINE D.O.O.	HR
Avodart® 0,5 mg Weichkapseln	SE/H/0471/001	60791.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Avodart 0,5 mg mjuka kapslar	SE/H/0471/001	21029	GLAXO GROUP LIMITED	SE
Combodart 0,5 mg/0,4 mg kietosios kapsulės	DE/H/2251/001	LT/1/10/2032/001	GLAXOSMITHKLINE LIETUVA UAB	LT
Combodart 0,5 mg/0,4 mg kietosios kapsulės	DE/H/2251/001	LT/1/10/2032/002	GLAXOSMITHKLINE LIETUVA UAB	LT
Combodart 0,5 mg/0,4 mg kietosios kapsulės	DE/H/2251/001	LT/1/10/2032/003	GLAXOSMITHKLINE LIETUVA UAB	LT
Combodart 0,5 mg / 0,4 mg harde capsules	DE/H/2251/001	BE369774	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Combodart 0,5 mg/0,4 mg Hartkapseln	DE/H/2251/001	BE369774	GLAXOSMITHKLINE	BE

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			PHARMACEUTICALS SA	
Duodart 0,5 mg/0,4 mg hårda kapslar	DE/H/2251/001	27116	GLAXOSMITHKLINE OY	FI
Duodart 0,4 mg/0,5 mg kemény kapszula	DE/H/2251/001	OGYI-T-21305/02	GLAXOSMITHKLINE KFT.	HU
Combodart 0,5 mg/0,4 mg trde kapsule	DE/H/2251/001	H/10/00410/002	GLAXOSMITHKLINE D.O.O.	SI
Combodart 0,5 mg/0,4 mg trde kapsule	DE/H/2251/001	H/10/00410/003	GLAXOSMITHKLINE D.O.O.	SI
Combodart 0,5 mg / 0,4 mg, gélules	DE/H/2251/001	2010 07 0103	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Duodart 0,5 mg/0,4 mg Hartkapseln	DE/H/2251/001	1-29401	GLAXOSMITHKLINE PHARMA GMBH.	AT
Combodart 0,5 mg / 0,4 mg, gélules	DE/H/2251/001	BE369774	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Дуодарт 0,5 mg / 0,4 mg твърди капсули	DE/H/2251/001	20100347	GLAXOSMITHKLINE EOOD	BG
Duodart 0,5 mg / 0,4 mg σκληρά καψάκια	DE/H/2251/001	20719	GLAXOSMITHKLINE (CYPRUS) LIMITED	CY
Duodart 0,5 mg/0,4 mg, tvrdé tobolky	DE/H/2251/001	87/349/10-C	GLAXOSMITHKLINE S.R.O.	CZ
Combodart, hårde kapsler	DE/H/2251/001	44502	GLAXOSMITHKLINE PHARMA A/S	DK
Combodart 0,5 mg/0,4 mg kõvakapslid	DE/H/2251/001	682110	GLAXOSMITHKLINE EESTI OÜ	EE
Duodart 0,5 mg/0,4 mg kovat kapselit	DE/H/2251/001	27116	GLAXOSMITHKLINE OY	FI
COMBODART 0,5 mg/0,4 mg, gélule	DE/H/2251/001	NL37589	LABORATOIRE GLAXOSMITHKLINE	FR
Duodart 0,5 mg/0,4 mg Hartkapseln	DE/H/2251/001	76877.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Duodart 0,5 mg / 0,4 mg σκληρά καψάκια	DE/H/2251/001	2863201	GLAXOSMITHKLINE AEBE	GR
Duodart 0,4 mg/0,5 mg kemény kapszula	DE/H/2251/001	OGYI-T-21305/01	GLAXOSMITHKLINE KFT.	HU

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Duodart 0,5 mg/0,4 mg hörð hylki	DE/H/2251/001	IS/1/09/046/01	GLAXOSMITHKLINE PHARMA A/S	IS
Combodart 0.5 mg / 0.4 mg hard capsules	DE/H/2251/001	PA 1077/118/001	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Combodart 0,5 mg / 0,4 mg capsule rigide	DE/H/2251/001	039913013	GLAXOSMITHKLINE S.P.A.	IT
Combodart 0,5 mg / 0,4 mg capsule rigide	DE/H/2251/001	039913025	GLAXOSMITHKLINE S.P.A.	IT
Combodart 0,5 mg / 0,4 mg capsule rigide	DE/H/2251/001	039913037	GLAXOSMITHKLINE S.P.A.	IT
Combodart 0,5 mg / 0,4 mg cietās kapsulas	DE/H/2251/001	10-0254	GLAXOSMITHKLINE LATVIA SIA	LV
Combodart 0.5 mg / 0.4 mg hard capsules	DE/H/2251/001	MA 300/00401	GLAXOSMITHKLINE UK LIMITED	MT
Combodart 0,5 mg/0,4 mg harde capsules	DE/H/2251/001	RVG 104130	GLAXOSMITHKLINE B.V.	NL
Duodart 0,5 mg / 0,4 mg harde kapsler	DE/H/2251/001	08-6438	GLAXOSMITHKLINE AS	NO
Duodart, 0,5 mg + 0,4 mg, kapsutki twarde	DE/H/2251/001	17029	GLAXOSMITHKLINE EXPORT LTD	PL
Combodart 0,5 mg / 0,4 mg cápsulas	DE/H/2251/001	5286570	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Combodart 0,5 mg / 0,4 mg cápsulas	DE/H/2251/001	5286562	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Duodart 0,5 mg/0,4 mg tvrdé kapsuly	DE/H/2251/001	77/0268/10-S	GLAXOSMITHKLINE SLOVAKIA S.R.O.	SK
Combodart 0,5 mg/0,4 mg trde kapsule	DE/H/2251/001	H/10/00410/001	GLAXOSMITHKLINE D.O.O.	SI
Duodart 0,5 mg/0,4 mg cápsulas duras	DE/H/2251/001	72.275	GLAXOSMITHKLINE, S.A.	ES
Combodart 0.5 mg / 0.4 mg hard	DE/H/2251/001	PL 19494/0046	GLAXOSMITHKLINE UK	UK

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capsules			LIMITED	
Duodart 0,5 mg/0,4 mg capsule	DE/H/2251/001	8163/2015/01	GLAXOSMITHKLINE (GSK) S.R.L.	RO
Duodart 0,5 mg/0,4 mg capsule	DE/H/2251/001	8163/2015/02	GLAXOSMITHKLINE (GSK) S.R.L.	RO
Duodart 0,5 mg/0,4 mg capsule	DE/H/2251/001	8163/2015/03	GLAXOSMITHKLINE (GSK) S.R.L.	RO
Avodart 0.5 mg soft capsules	PL 19494/0006	SE/H/0304/001	GLAXOSMITHKLINE UK LIMITED	UK