



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 July 2023
EMA/319544/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): dutasteride, dutasteride / tamsulosine

Procedure No. PSUSA/00010506/202211



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
Aglandin comp. 0,5 mg/0,4 mg-Hartkapseln	not available	138633	G.L. PHARMA GMBH	AT
Avodart 0,5 mg Weichkapseln	SE/H/0304/001	1-24844	GLAXOSMITHKLINE PHARMA GMBH.	AT
Dutaglandin comp. 0,5 mg/0,4 mg-Hartkapseln	ES/H/0465/001	138457	G.L. PHARMA GMBH	AT
DuTamsul 0,5 mg/0,4 mg Hartkapseln	ES/H/0466/001	138456	GENERICON PHARMA GESELLSCHAFT M.B.H.	AT
Avodart 0,5 mg capsules molles	SE/H/0304/001	BE250381	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Avodart 0,5 mg Weichkapseln Dutasterid	SE/H/0304/001	BE250381	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Avodart 0,5 mg zachte capsules	SE/H/0304/001	BE250381	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
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, gélules	DE/H/2251/001	BE369774	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Combodart 0,5 mg/0,4 mg Hartkapseln	DE/H/2251/001	BE369774	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Duodart 0,5 mg / 0,4 mg hard capsules	DE/H/2251/001	20100347	GLAXOSMITHKLINE TRADING SERVICES LIMITED	BG
Агландин комп 0,5 mg/0,4 mg твърди капсули	ES/H/0465/001	20180350	G.L. PHARMA GMBH	BG
Дутапростам 0,5 mg/ 0,4 mg твърди капсули	IS/H/0538/001	20180352	ALVOGEN MALTA OPERATIONS (ROW) LTD	BG

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Тамстерид 0,5 mg/0,4 mg капсули, твърди	not available	20190163	ECOPHARM GROUP	BG
Уримакс Duo 0,5 mg/0,4 mg твърди капсули	not available	20180125	SOPHARMA AD	BG
Avodart 0,5 mg μαλακά καψάκια.	SE/H/0304/001	19719	GLAXOSMITHKLINE (IRELAND) LIMITED	CY
Duodart 0,5 mg / 0,4 mg σκληρά καψάκια	DE/H/2251/001	20719	GLAXOSMITHKLINE TRADING SERVICES LIMITED	CY
Atucare 0,5 mg/0,4 mg tvrdé tobolky	CZ/H/0864/001	87/154/18-C	HEATON K.S.	CZ
Avodart 0,5 mg mekké tobolky	SE/H/0304/001	87/287/03-C	GLAXOSMITHKLINE (IRELAND) LIMITED	CZ
Duodart 0,5 mg/0,4 mg, tvrdé tobolky	DE/H/2251/001	87/349/10-C	GLAXOSMITHKLINE S.R.O.	CZ
Avodart 0,5 mg Weichkapseln	SE/H/0304/001	55613.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Duodart 0,5 mg/0,4 mg Hartkapseln	DE/H/2251/001	76877.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Dutasterid-Tamsulosinhydrochlorid GlaxoSmithKline 0,5 mg/0,4 mg Hartkapseln	DE/H/2252/001	76878.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Avodart, 0,5 mg pehmekapslid	SE/H/0304/001	421703	GLAXOSMITHKLINE TRADING SERVICES LIMITED	EE
Combodart 0,5 mg/0,4 mg kõvakapslid	DE/H/2251/001	682110	GLAXOSMITHKLINE TRADING SERVICES LIMITED	EE
Dutamsin 0,5 mg/0,4 mg kõvakapslid	ES/H/0465/001	972418	G.L. PHARMA GMBH	EE
Avidart 0,5 mg cápsulas blandas	SE/H/0304/001	65.178	GLAXOSMITHKLINE, S.A.	ES

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Duodart 0,5 mg/0,4 mg cápsulas duras	DE/H/2251/001	72.275	GLAXOSMITHKLINE, S.A.	ES
Dutamsin 0,5 mg/0,4 mg, cápsulas duras	ES/H/0466/001/DC	83630	EXELTIS HEALTHCARE S.L	ES
Dutasterida/Tamsulosina Almus Pharma 0,5 mg/0,4 mg cápsulas duras	not available	83704	ALMUS FARMACÉUTICA, S.A.U.	ES
Dutasterida/Tamsulosina Alter Genéricos 0,5 mg/0,4 mg cápsulas duras	not available	83.701	LABORATORIOS ALTER, S.A.	ES
dutasterida/tamsulosina cinfamed 0,5 mg/0,4 mg cápsulas duras	not available	83705	LABORATORIOS CINFA, S.A.	ES
Dutasterida/Tamsulosina Normon 0,5 mg/0,4 mg cápsulas duras	not available	83699	LABORATORIOS NORMON, S.A.	ES
Dutasterida/Tamsulosina Qualigen 0,5 mg/0,4 mg cápsulas duras.	not available	83707	NEURAXPHARM SPAIN, S.L.U.	ES
Dutasterida/Tamsulosina Tarbis 0,5 mg/0,4 mg cápsulas duras	not available	83700	TARBIS FARMA, S.L.	ES
Dutasterida/Tamsulosina Teva 0,5 mg/0,4 mg capsulas duras	ES/H/0465/001	83557	TEVA B.V	ES
Ilmago 0,5 mg/ 0,4 mg cápsulas duras	not available	83753	LABORATORIOS SALVAT, S.A.	ES
Neomyx 0,5 mg/0,4 mg cápsulas duras	not available	83.698	LABORATORIOS ALTER, S.A.	ES
Taduman 0,5 mg/0,4 mg cápsulas duras	not available	83.706	MANA PHARMA, S.L.	ES

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Avodart 0,5 mg mjuka kapslar	SE/H/0304/001	19814	GLAXOSMITHKLINE OY	FI
Avodart 0,5 mg pehmeät kapselit	SE/H/0304/001	19814	GLAXOSMITHKLINE OY	FI
Duodart 0,5 mg/0,4 mg hårda kapslar	DE/H/2251/001	27116	GLAXOSMITHKLINE OY	FI
Duodart 0,5 mg/0,4 mg kovat kapselit	DE/H/2251/001	27116	GLAXOSMITHKLINE OY	FI
AVODART 0,5 mg, capsule molle	SE/H/0304/001	NL28131	LABORATOIRE GLAXOSMITHKLINE	FR
COMBODART 0,5 mg/0,4 mg, gélule	DE/H/2251/001	NL37589	LABORATOIRE GLAXOSMITHKLINE	FR
Avodart 0,5 mg μαλακά καψάκια	SE/H/0304/001	2578701	GLAXOSMITHKLINE SINGLE MEMBER A.E.B.E.	GR
Duagen 0,5 mg μαλακά καψάκια	SE/H/0305/001	2578801	GLAXOSMITHKLINE SINGLE MEMBER A.E.B.E.	GR
Duodart 0,5 mg / 0,4 mg σκληρά καψάκια	DE/H/2251/001	2863201	GLAXOSMITHKLINE SINGLE MEMBER A.E.B.E.	GR
Avodart 0,5 mg meke kapsule	not available	HR-H-357757654	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HR
Duodart 0,5 mg/0,4 mg tvrde kapsule	not available	HR-H-979570583	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HR
Avodart 0,5 mg lágy kapszula	SE/H/0304/001	OGYI-T-9079/01	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HU
Avodart 0,5 mg lágy kapszula	SE/H/0304/001	OGYI-T-9079/02	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HU
Avodart 0,5 mg lágy kapszula	SE/H/0304/001	OGYI-T-9079/03	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HU

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Avodart 0,5 mg lágy kapszula	SE/H/0304/001	OGYI-T-9079/04	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HU
Duodart 0,4 mg/0,5 mg kemény kapszula	DE/H/2251/001	OGYI-T-21305/02	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HU
Duodart 0,4 mg/0,5 mg kemény kapszula	DE/H/2251/001	OGYI-T-21305/01	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HU
Avodart 0.5 mg soft capsules	SE/H/0304/001	PA1077/104/001	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Combodart 0.5 mg / 0.4 mg hard capsules	DE/H/2251/001	PA 1077/118/001	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Duodart 0,5 mg/0,4 mg hörð hylki	DE/H/2251/001	IS/1/09/046/01	GLAXOSMITHKLINE PHARMA A/S	IS
Dutaprostam 0,5 mg/0,4 mg hörð hylki	IS/H/0538/001	IS/1/18/093/01	ZENTIVA, K.S.	IS
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
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
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

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
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
Avodart 0,5 mg minkštosios kapsulės	SE/H/0304/001	LT/1/06/0475/001	GLAXOSMITHKLINE (IRELAND) LIMITED	LT
Avodart 0,5 mg minkštosios kapsulės	SE/H/0304/001	LT/1/06/0475/002	GLAXOSMITHKLINE (IRELAND) LIMITED	LT
Avodart 0,5 mg minkštosios kapsulės	SE/H/0304/001	LT/1/06/0475/003	GLAXOSMITHKLINE (IRELAND) LIMITED	LT
Avodart 0,5 mg minkštosios kapsulės	SE/H/0304/001	LT/1/06/0475/005	GLAXOSMITHKLINE (IRELAND) LIMITED	LT
Avodart 0,5 mg minkštosios kapsulės	SE/H/0304/001	LT/1/06/0475/004	GLAXOSMITHKLINE (IRELAND) LIMITED	LT
Combodart 0,5 mg/0,4 mg kietosios kapsulės	DE/H/2251/001	LT/1/10/2032/003	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Combodart 0,5 mg/0,4 mg kietosios kapsulės	DE/H/2251/001	LT/1/10/2032/001	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Combodart 0,5 mg/0,4 mg kietosios kapsulės	DE/H/2251/001	LT/1/10/2032/002	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Avodart 0,5 mg capsules molles	SE/H/0304/001	2008 01 9608	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Avodart 0,5 mg Weichkapseln Dutasterid	SE/H/0304/001	2008 01 9608	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Combodart 0,5 mg / 0,4 mg, gélules	DE/H/2251/001	2010 07 0103	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU

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
Avodart 0,5 mg mīkstās kapsulas	SE/H/0304/001	04-0410	GLAXOSMITHKLINE (IRELAND) LIMITED	LV
Combodart 0,5 mg / 0,4 mg cietas kapsulas	DE/H/2251/001	10-0254	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LV
Dutamsin 0,5 mg / 0,4 mg cietas kapsulas	ES/H/0465/001	18-0137	G.L. PHARMA GMBH	LV
Atucare 0.5 mg/0.4 mg hard capsules	CZ/H/0864/001	MA1006/01101	HEATON K.S.	MT
Avodart 0.5 mg soft capsules	SE/H/0304/001	MA192/02701	GLAXOSMITHKLINE (IRELAND) LIMITED	MT
Combodart 0.5 mg / 0.4 mg hard capsules	DE/H/2251/001	MA192/02601	GLAXOSMITHKLINE (IRELAND) LIMITED	MT
Avodart 0,5 mg zachte capsules	SE/H/0304/001	RVG 28317	GLAXOSMITHKLINE B.V.	NL
Combodart 0,5 mg/0,4 mg harde capsules	DE/H/2251/001	RVG 104130	GLAXOSMITHKLINE B.V.	NL
Dutasteride/Tamsulosine HCl 0,5 mg/0,4 mg Focus, harde capsules	ES/H/0466/001	RVG 120494	FOCUS CARE PHARMACEUTICALS B.V.	NL
Avodart 0,5 mg myke kapsler	SE/H/0304/001	02-1382	GLAXOSMITHKLINE AS	NO
Duodart 0,5 mg / 0,4 mg harde kapsler	DE/H/2251/001	08-6438	GLAXOSMITHKLINE AS	NO
Adatam Duo, 0,5 mg + 0,4 mg, kapsuļki twarde	ES/H/0465/001	25732	ADAMED PHARMA S.A.	PL
Avodart, 0,5 mg, kapsulki miekkie	SE/H/0304/001	11165	GLAXOSMITHKLINE (IRELAND) LIMITED	PL
Duodart, 0,5 mg + 0,4 mg, kapsuļki twarde	DE/H/2251/001	17029	GLAXOSMITHKLINE (IRELAND) LIMITED	PL

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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
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
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
Dutasterida + Tansulosina Generis 0,5 mg + 0,4 mg cápsulas	not available	5759857	GENERIS FARMACÊUTICA, S.A.	PT
Dutasterida + Tansulosina Generis 0,5 mg + 0,4 mg cápsulas	not available	5759865	GENERIS FARMACÊUTICA, S.A.	PT
Dutasterida + Tansulosina Generis 0,5 mg + 0,4 mg cápsulas	not available	5759873	GENERIS FARMACÊUTICA, S.A.	PT

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Dutasterida + Tansulosina Pharmakern 0,5 mg + 0,4 mg cápsulas	not available	5760202	PHARMAKERN PORTUGAL – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA.	PT
Dutasterida + Tansulosina Pharmakern 0,5 mg + 0,4 mg cápsulas	not available	5760210	PHARMAKERN PORTUGAL – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA.	PT
ILMAGO 0,5 mg + 0,4 mg cápsulas	not available	5796545	LABORATORIOS SALVAT, S.A.	PT
Juteo 0,5 mg / 0,4 mg cápsulas	DE/H/2252/001	5284955	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
Juteo 0,5 mg / 0,4 mg cápsulas	DE/H/2252/001	5284948	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
Sarix 0,5 mg + 0,4 mg cápsulas	ES/H/0466/001	5760053	LABORATÓRIOS ATRAL, S.A.	PT
Sarix 0,5 mg + 0,4 mg cápsulas	ES/H/0466/001	5760061	LABORATÓRIOS ATRAL, S.A.	PT
Sarix 0,5 mg + 0,4 mg cápsulas	ES/H/0466/001	5760079	LABORATÓRIOS ATRAL, S.A.	PT
Avodart 0,5 mg capsule moi	SE/H/0304/001	7029/2014/01	GLAXOSMITHKLINE TRADING SERVICES LIMITED	RO
Avodart 0,5 mg capsule moi	SE/H/0304/001	7029/2014/02	GLAXOSMITHKLINE TRADING SERVICES LIMITED	RO
Avodart 0,5 mg capsule moi	SE/H/0304/001	7029/2014/03	GLAXOSMITHKLINE TRADING SERVICES LIMITED	RO
Avodart 0,5 mg capsule moi	SE/H/0304/001	7029/2014/04	GLAXOSMITHKLINE TRADING SERVICES LIMITED	RO
Avodart 0,5 mg capsule moi	SE/H/0304/001	7029/2014/05	GLAXOSMITHKLINE TRADING SERVICES LIMITED	RO
Duodart 0,5 mg/0,4 mg capsule	DE/H/2251/001	8163/2015/01	GLAXOSMITHKLINE TRADING SERVICES LIMITED	RO

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Duodart 0,5 mg/0,4 mg capsule	DE/H/2251/001	8163/2015/02	GLAXOSMITHKLINE TRADING SERVICES LIMITED	RO
Duodart 0,5 mg/0,4 mg capsule	DE/H/2251/001	8163/2015/03	GLAXOSMITHKLINE TRADING SERVICES LIMITED	RO
Rimril 0,5 mg/0,4 mg capsule	CZ/H/0864/001	13352/2020/01	HEATON K.S.	RO
Rimril 0,5 mg/0,4 mg capsule	CZ/H/0864/001	13352/2020/02	HEATON K.S.	RO
Rimril 0,5 mg/0,4 mg capsule	CZ/H/0864/001	13352/2020/03	HEATON K.S.	RO
Avodart 0,5 mg mjuka kapslar	SE/H/0471/001	21029	GLAXOSMITHKLINE (IRELAND) LIMITED	SE
Avodart 0,5 mg mjuka kapslar	SE/H/0304/001	17871	GLAXOSMITHKLINE (IRELAND) LIMITED	SE
Duagen 0,5 mg mjuka kapslar	SE/H/0305/001	17872	GLAXOSMITHKLINE (IRELAND) LIMITED	SE
Avodart 0,5 mg mehke kapsule	SE/H/0304/001	H/04/00243/001	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
Avodart 0,5 mg mehke kapsule	SE/H/0304/001	H/04/00243/003	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
Avodart 0,5 mg mehke kapsule	SE/H/0304/001	H/04/00243/004	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
Avodart 0,5 mg mehke kapsule	SE/H/0304/001	H/04/00243/005	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
Avodart 0,5 mg mehke kapsule	SE/H/0304/001	H/04/00243/002	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
Combodart 0,5 mg/0,4 mg trde kapsule	DE/H/2251/001	H/10/00410/002	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI

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Combodart 0,5 mg/0,4 mg trde kapsule	DE/H/2251/001	H/10/00410/003	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
Combodart 0,5 mg/0,4 mg trde kapsule	DE/H/2251/001	H/10/00410/001	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
Atucare 0,5 mg/0,4 mg tvrdé kapsuly	CZ/H/0864/001	77/0023/20-S	HEATON K.S.	SK
Avodart 0,5 mg mäkké kapsuly	SE/H/0304/001	87/0286/04-S	GLAXOSMITHKLINE (IRELAND) LIMITED	SK
Duodart 0,5 mg/0,4 mg tvrdé kapsuly	DE/H/2251/001	77/0268/10-S	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SK