

Annex I
List of medicinal products and presentations

A. List of medicinal products and presentations recommended for variation

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Austria	+pharma Arzneimittel Gmbh	Finasterid +pharma	finasteride	5 mg	film-coated tablet	oral use
Austria	+pharma Arzneimittel Gmbh	Tamsuduo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Austria	A-Med Gmbh	Finasterid A-Med	finasteride	5 mg	film-coated tablet	oral use
Austria	Accord Healthcare B.V.	Dutasterid Accord	dutasteride	0.5 mg	capsule, soft	oral use
Austria	Actavis Group Ptc Ehf.	Finasterid Actavis	finasteride	5 mg	film-coated tablet	oral use
Austria	Aristo Pharma Gmbh	Finasterid Aristo	finasteride	5 mg	film-coated tablet	oral use
Austria	G.L. Pharma Gmbh	Dutaglandin Comp.	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Austria	G.L. Pharma Gmbh	Dutasterid Lannacher	dutasteride	0.5 mg	capsule, soft	oral use
Austria	G.L. Pharma Gmbh	Finasterid G.L.	finasteride	5 mg	film-coated tablet	oral use
Austria	G.L. Pharma Gmbh	Androfin	finasteride	5 mg	film-coated tablet	oral use
Austria	G.L. Pharma Gmbh	Dutaglandin	dutasteride	0.5 mg	capsule, soft	oral use
Austria	Genericon Pharma Gesellschaft M.B.H.	Finasterid Genericon	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Austria	Genericon Pharma Gesellschaft M.B.H.	Dutamsul	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Austria	Genericon Pharma Gesellschaft M.B.H.	Dutasterid Genericon	dutasteride	0.5 mg	capsule, soft	oral use
Austria	Glaxosmithkline Pharma Gmbh.	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Austria	Hexal Pharma Gmbh	Finasterid Hexal	finasteride	5 mg	film-coated tablet	oral use
Austria	Interpharm Produktions Gmbh	Finasterid Interpharm	finasteride	5 mg	film-coated tablet	oral use
Austria	Organon healthcare Gmbh	Propecia	finasteride	1 mg	film-coated tablet	oral use
Austria	Organon healthcare Gmbh	Proscar	finasteride	5 mg	film-coated tablet	oral use
Austria	Sandoz Gmbh	Finasterid Sandoz	finasteride	5 mg	film-coated tablet	oral use
Austria	Stada Arzneimittel Gmbh	Finasterid Stada	finasteride	5 mg	film-coated tablet	oral use
Austria	Teva B.V	Finasteride Ratiopharm	finasteride	5 mg	film-coated tablet	oral use
Belgium	Aurobindo N.V.	Dutasteride Ab	dutasteride	0.5 mg	capsule, soft	oral use
Belgium	Aurobindo N.V.	Dutasteride/ Tamsulosine Hcl Ab	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Belgium	Eurogenerics N.V./S.A.	Dutasteride/ Tamsulosine Eg	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Belgium	Eurogenerics N.V./S.A.	Dutasteride/ Tamsulosine Eg	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Belgium	Eurogenerics N.V./S.A.	Finasteride Eg	finasteride	5 mg	film-coated tablet	oral use
Belgium	Glaxosmithkline Pharmaceuticals En Abrege Glaxosmithkline	Combodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Belgium	Glaxosmithkline Pharmaceuticals En Abrege Glaxosmithkline	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Belgium	Krka, D.D., Novo Mesto	Dutasteride Krka	dutasteride	0.5 mg	capsule, soft	oral use
Belgium	Organon Belgium	Proscar	finasteride	5 mg	film-coated tablet	oral use
Belgium	Sandoz N.V.	Dutasteride Sandoz	dutasteride	0.5 mg	capsule, soft	oral use
Belgium	Sandoz N.V.	Dutasteride/ Tamsulosine Sandoz	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Belgium	Teva B.V	Dutasteride/ Tamsulosine Teva	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Belgium	Teva Pharma Belgium N.V./S.A	Finasteride Teva	finasteride	5 mg	film-coated tablet	oral use
Belgium	Viatrix Gx	Finasteride Viatrix	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Belgium	Viatrix Gx	Dutasteride/ Tamsulosine Viatrix	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Bulgaria	Accord Healthcare Polska Sp. Z O.O.	Финастерид Акорд	finasteride	5 mg	film-coated tablet	oral use
Bulgaria	Accord Healthcare Polska Sp. Z O.O.	Дутастерид Акорд	dutasteride	0.5 mg	capsule, soft	oral use
Bulgaria	Alkaloid-Int D.O.O.	Тамализ Дуод	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Bulgaria	Ecopharm Group	Тамстерид	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Bulgaria	G.L. Pharma Gmbh	Агландин Комп	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Bulgaria	Glaxosmithkline Trading Services Limited	Дуодарт	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Bulgaria	Krka, D.D., Novo Mesto	Дутрис	dutasteride	0.5 mg	capsule, soft	oral use
Bulgaria	Neo Balkanika Ltd.	Финастерид Нео Balkanika Eood	finasteride	5 mg	film-coated tablet	oral use
Bulgaria	Sopharma Ad	Уримакс Дуо	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Bulgaria	Stada Arzneimittel Ag	Тамсударт	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Bulgaria	Teva B.V	Хиплафин	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Bulgaria	Teva B.V	Тамсудил Дуо	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Bulgaria	Viartis Limited	Дутамайл	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Bulgaria	Zentiva, K.S.	Дутрозен	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Bulgaria	Zentiva, K.S.	Пенестер	finasteride	5 mg	film-coated tablet	oral use
Croatia	Accord Healthcare Polska Sp. Z O.O.	Dutasterid/ Tamsulozin Accord	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Croatia	Accord Healthcare Polska Sp. Z O.O.	Dutasterid Accord	dutasteride	0.5 mg	capsule, soft	oral use
Croatia	Alkaloid-Int D.O.O.	Tamaliz Duo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Croatia	Alpha-Medical D.O.O.	Duostin	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Croatia	Belupo D.D.	Klilotas	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Croatia	Genericon Pharma Gesellschaft M.B.H.	Dutasterid Genericon	dutasteride	0.5 mg	capsule, soft	oral use
Croatia	Genericon Pharma Gesellschaft M.B.H.	Finasterid Genericon	finasteride	5 mg	film-coated tablet	oral use
Croatia	Genericon Pharma Gesellschaft M.B.H.	Duitam	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Croatia	Glaxosmithkline Trading Services Limited	Duodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Croatia	Glaxosmithkline Trading Services Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Croatia	Krka-Farma D.O.O.	Dutrys	dutasteride	0.5 mg	capsule, soft	oral use
Croatia	Krka-Farma D.O.O.	Finpros	finasteride	5 mg	film-coated tablet	oral use
Croatia	Krka-Farma D.O.O.	Dutamyz	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Croatia	Organon Pharma Društvo S Ograničenom Odgovornošću za Trgovinu I Usluge	Proscar	finasteride	5 mg	film-coated tablet	oral use
Croatia	Pharmas	Atekago	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Croatia	Pharmas	Fincar	finasteride	5 mg	film-coated tablet	oral use
Croatia	Pharmas D.O.O.	Finasterid Pharmas	finasteride	5 mg	film-coated tablet	oral use
Croatia	Pliva Hrvatska D.O.O.	Mostrafin	finasteride	5 mg	film-coated tablet	oral use
Croatia	Pliva Hrvatska D.O.O.	Duster	dutasteride	0.5 mg	capsule, soft	oral use
Croatia	Pliva Hrvatska D.O.O.	Duster Duo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Croatia	Stada D.O.O.	Dutasteridum Stada	dutasteride	0.5 mg	capsule, soft	oral use
Croatia	Stada D.O.O.	Dutasterid/ Tamsulozin Stada	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Croatia	Viatriis Limited	Vasgar	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Croatia	Zentiva, K.S.	Dupro	dutasteride	0.5 mg	capsule, soft	oral use
Croatia	Zentiva, K.S.	Dupro Plus	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Cyprus	Accord Healthcare S.L.U.	Finasteride Accord	finasteride	5 mg	film-coated tablet	oral use
Cyprus	Accord Healthcare S.L.U.	Finasteride Accord	finasteride	1 mg	film-coated tablet	oral use
Cyprus	Aurobindo Pharma (Malta) Limited	Finasterid Aurobindo	finasteride	5 mg	film-coated tablet	oral use
Cyprus	Elpen Pharmaceutical Co. Inc.	Dinaplex	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Cyprus	Glaxosmithkline (Ireland) Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Cyprus	Glaxosmithkline Trading Services Limited	Duodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Cyprus	Laboratoires Bailleul S.A.	Andropecia	finasteride	1 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Cyprus	N.V. Organon	Propecia	finasteride	1 mg	film-coated tablet	oral use
Cyprus	Rafarm S.A.	Rafuster	dutasteride	0.5 mg	capsule, soft	oral use
Czech Republic	+pharma Arzneimittel Gmbh	Hyplafin	finasteride	5 mg	film-coated tablet	oral use
Czech Republic	+pharma Arzneimittel Gmbh	Duitam	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Czech Republic	Accord Healthcare Polska Sp. Z O.O.	Dustar	dutasteride	0.5 mg	capsule, soft	oral use
Czech Republic	Adamed Pharma S.A.	Adadut	dutasteride	0.5 mg	capsule, soft	oral use
Czech Republic	Adamed Pharma S.A.	Adatam	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Czech Republic	Ardez Pharma	Finard	finasteride	5 mg	film-coated tablet	oral use
Czech Republic	Ardez Pharma	Tedez	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Czech Republic	Ardez Pharma	Dutamon	dutasteride	0.5 mg	capsule, soft	oral use
Czech Republic	Aristo Pharma Gmbh	Finasterid Aristo	finasteride	5 mg	film-coated tablet	oral use
Czech Republic	Aristo Pharma Gmbh	Marumax	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Czech Republic	Aristo Pharma Gmbh	Dutasterid Aristo	dutasteride	0.5 mg	capsule, soft	oral use
Czech Republic	Belupo D.D.	Dubelotam	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Czech Republic	Cande Cz S.R.O.	Milten	finasteride	5 mg	film-coated tablet	oral use
Czech Republic	Cande Cz S.R.O.	Ladurot	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Czech Republic	Cande Cz S.R.O.	Reneten	dutasteride	0.5 mg	capsule, soft	oral use
Czech Republic	Farmak International Sp. Z O.O.	Dutasterid/ Tamsulosin Fmk	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Czech Republic	G.L. Pharma Gmbh	Androfin	finasteride	5 mg	film-coated tablet	oral use
Czech Republic	G.L. Pharma Gmbh	Aglandut	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Czech Republic	G.L. Pharma Gmbh	Dutalan	dutasteride	0.5 mg	capsule, soft	oral use
Czech Republic	Glaxosmithkline (Ireland) Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Czech Republic	Glaxosmithkline S.R.O.	Duodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Czech Republic	Heaton K.S.	Atucare	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Czech Republic	Hexal Ag	Finex	finasteride	5 mg	film-coated tablet	oral use
Czech Republic	Krka, D.D., Novo Mesto	Finpros	finasteride	5 mg	film-coated tablet	oral use
Czech Republic	Krka, D.D., Novo Mesto	Tadustix	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Czech Republic	Sandoz S.R.O.	Dutacomp	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Czech Republic	Viatriis Limited	Finasterid Viatriis	finasteride	5 mg	film-coated tablet	oral use
Czech Republic	Viatriis Limited	Taris	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Czech Republic	Vipfarm S.A.	Alkapidan	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Czech Republic	Vipfarm S.A.	Finanorm	finasteride	5 mg	film-coated tablet	oral use
Czech Republic	Zentiva, K.S.	Penester	finasteride	5 mg	film-coated tablet	oral use
Czech Republic	Zentiva, K.S.	Dutrozen	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Denmark	2care4 Generics ApS	Prosterid	finasteride	1 mg	film-coated tablet	oral use
Denmark	Alkaloid-Int D.O.O.	Dutasterid "alkaloid"	dutasteride	0.5 mg	capsule, soft	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Denmark	Amarox Pharma B.V.	Finasterid Amarox	finasteride	5 mg	film-coated tablet	oral use
Denmark	Aurobindo Pharma (Malta) Limited	Finasterid Aurobindo	finasteride	5 mg	film-coated tablet	oral use
Denmark	Betapharm Arzneimittel Gmbh	Dutasterid/ Tamsulosinhydrochlorid Betapharm	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Denmark	Exeltis Healthcare S.L	Unisol	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Denmark	G.L. Pharma Gmbh	Dutasterid/ Tamsulosinhydrochlorid G.L. Pharma	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Denmark	G.L. Pharma Gmbh	Lanadut	dutasteride	0.5 mg	capsule, soft	oral use
Denmark	Glenmark Arzneimittel Gmbh	Dutasterid/ Tamsulosinhydrochlorid Glenmark	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Denmark	Hexal A/S	Dutasterid "hexal"	dutasteride	0.5 mg	capsule, soft	oral use
Denmark	Krka, D.D., Novo Mesto	Dutasteride Krka	dutasteride	0.5 mg	capsule, soft	oral use
Denmark	Krka, D.D., Novo Mesto	Dutrys	dutasteride	0.5 mg	capsule, soft	oral use
Denmark	Laboratorios León Farma, S.A.	Dutastem	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Denmark	Laboratorios León Farma, S.A.	Prostaduo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Denmark	Laboratorios León Farma, S.A.	Dutasterid Laboratorios León Farma	dutasteride	0.5 mg	capsule, soft	oral use
Denmark	Laboratorios León Farma, S.A.	Dutatex	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Denmark	Laboratorios León Farma, S.A.	Duotam	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Denmark	Laboratorios León Farma, S.A.	Hydutam	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Denmark	Laboratorios León Farma, S.A.	Dutamsine	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Denmark	Laboratorios León Farma, S.A.	Denerid	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Denmark	Laboratorios Liconsa, S.A.	Dutasterid Laboratorios Liconsa	dutasteride	0.5 mg	capsule, soft	oral use
Denmark	Laboratorios Liconsa, S.A.	Dutasterid "liconsa"	dutasteride	0.5 mg	capsule, soft	oral use
Denmark	Laboratorios Liconsa, S.A.	Deridust	dutasteride	0.5 mg	capsule, soft	oral use
Denmark	Medical Valley Invest Ab	Finasteride Medical Valley	finasteride	5 mg	film-coated tablet	oral use
Denmark	Medical Valley Invest Ab	Dutasteride Medical Valley	dutasteride	0.5 mg	capsule, soft	oral use
Denmark	Medical Valley Invest Ab	Duta Tamsaxiro	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Denmark	Stada Arzneimittel Ag	Finastad	finasteride	1 mg	film-coated tablet	oral use
Denmark	Stada Arzneimittel Ag	Dutasteride/ Tamsulosinhydrochloride Stada	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Denmark	Stada Arzneimittel Ag	Finasterid Stada	finasteride	5 mg	film-coated tablet	oral use
Denmark	Teva B.V	Finasteride Teva	finasteride	5 mg	film-coated tablet	oral use
Denmark	Teva B.V	Dutasteride Teva	dutasteride	0.5 mg	capsule, soft	oral use
Denmark	Teva B.V	Finasteride Teva	finasteride	1 mg	film-coated tablet	oral use
Denmark	Universal Farma, S.L.	Dutasterid Universal Farma	dutasteride	0.5 mg	capsule, soft	oral use
Denmark	Viatriis Limited	Dutasterid Mylan	dutasteride	0.5 mg	capsule, soft	oral use
Estonia	Accord Healthcare B.V.	Finasteride Accord	finasteride	5 mg	film-coated tablet	oral use
Estonia	Accord Healthcare B.V.	Finasteride Accord	finasteride	1 mg	film-coated tablet	oral use
Estonia	Glaxosmithkline Trading Services Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Estonia	Glaxosmithkline Trading Services Limited	Combodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Estonia	JSC Olainfarm	Dutasteride/ Tamsulosin Olainfarm	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Estonia	Krka, D.D., Novo Mesto	Tadusta	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Estonia	Sia Elvim	Dutasteride Elvim	dutasteride	0.5 mg	capsule, soft	oral use
Estonia	Teva B.V	Dutasteride/ Tamsulosin Teva	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Estonia	Teva Pharma B.V.	Dutasteride Teva	dutasteride	0.5 mg	capsule, soft	oral use
Estonia	Teva Pharma B.V.	Finasteride Teva	finasteride	5 mg	film-coated tablet	oral use
Estonia	Teva Pharma B.V.	Dutasteride Ratiopharm	dutasteride	0.5 mg	capsule, soft	oral use
Estonia	Viartis Limited	Dutasteride/ Tamsulosin Viartis	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Estonia	Zentiva, K.S.	Dutrozen	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Finland	2care4 Generics Aps	Prosterid	finasteride	1 mg	film-coated tablet	oral use
Finland	Glaxosmithkline Oy	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Finland	Glaxosmithkline Oy	Duodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Finland	Hexal A/S	Gefina	finasteride	5 mg	film-coated tablet	oral use
Finland	Krka, D.D., Novo Mesto	Dutasteride Krka	dutasteride	0.5 mg	capsule, soft	oral use
Finland	Medical Valley Invest Ab	Dutasteride Medical Valley	dutasteride	0.5 mg	capsule, soft	oral use
Finland	N.V. Organon	Propecia	finasteride	1 mg	film-coated tablet	oral use
Finland	N.V. Organon	Proscar	finasteride	5 mg	film-coated tablet	oral use
Finland	Orion Corporation	Dutasteride/ Tamsulosin Orion	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Finland	Orion Corporation	Finasterid Orion	finasteride	5 mg	film-coated tablet	oral use
Finland	Ratiopharm Gmbh	Finasterid Ratiopharm	finasteride	5 mg	film-coated tablet	oral use
Finland	Sandoz A/S	Dutester	dutasteride	0.5 mg	capsule, soft	oral use
Finland	Sandoz A/S	Dutasteride/ Tamsulosinhydrochloride Sandoz	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Finland	Stada Arzneimittel Ag	Dutasterid/Tamulosin Stada	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Finland	Teva B.V	Dutasteride/ Tamsulosinhydrochlorid Ratiopharm	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Finland	Teva Pharma B.V.	Dutasteride Ratiopharm	dutasteride	0.5 mg	capsule, soft	oral use
Finland	Viatriis Limited	Dutasteride Viatriis	dutasteride	0.5 mg	capsule, soft	oral use
Finland	Viatriis Limited	Dutasteride/ Tamsulosinhydrochloride Viatriis	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
France	Accord Healthcare France Sas	Dutasteride/ Tamsulosine Accord	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
France	Accord Healthcare France Sas	Finasteride Accord	finasteride	5 mg	film-coated tablet	oral use
France	Accord Healthcare France Sas	Dutasteride Accord	dutasteride	0.5 mg	capsule, soft	oral use
France	Almus France	Finasteride Almus	finasteride	5 mg	film-coated tablet	oral use
France	Amarox Pharma Gmbh	Finasteride AmaroX	finasteride	5 mg	film-coated tablet	oral use
France	Amarox Pharma Gmbh	Finasteride AmaroX	finasteride	1 mg	film-coated tablet	oral use
France	Arrow Generiques	Finasteride Arrow Lab	finasteride	5 mg	film-coated tablet	oral use
France	Arrow Generiques	Finasteride Arrow Generiques	finasteride	1 mg	film-coated tablet	oral use
France	Arrow Generiques	Finasteride Arrow Lab	finasteride	1 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
France	Arrow Generiques	Dutasteride/ Tamsulosine Arrow	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
France	Arrow Generiques	Dutasteride Arrow Lab	dutasteride	0.5 mg	capsule, soft	oral use
France	Axunio Pharma Gmbh	Finasteride Nio	finasteride	1 mg	film-coated tablet	oral use
France	Biogaran	Finasteride Biogaran	finasteride	1 mg	film-coated tablet	oral use
France	Biogaran	Dutasteride Biogaran	dutasteride	0.5 mg	capsule, soft	oral use
France	Biogaran	Dutasteride/ Tamsulosine Biogaran	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
France	Biogaran	Finasteride Biogaran	finasteride	5 mg	film-coated tablet	oral use
France	Cristers	Finasteride Cristers	finasteride	5 mg	film-coated tablet	oral use
France	Cristers	Dutasteride/ Tamsulosine Cristers	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, soft	oral use
France	Cristers	Finasteride Cristers	finasteride	1 mg	film-coated tablet	oral use
France	Cristers	Dutasteride Cristers	dutasteride	0.5 mg	capsule, soft	oral use
France	Eg Labo Laboratoires Eurogenerics	Finasteride Eg	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
France	Eg Labo Laboratoires Eurogenerics	Finasteride Eg	finasteride	1 mg	film-coated tablet	oral use
France	Eg Labo Laboratoires Eurogenerics	Dutasteride/ Tamsulosine Eg	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
France	Eg Labo Laboratoires Eurogenerics	Dutasteride Eg	dutasteride	0.5 mg	capsule, soft	oral use
France	Evolupharm	Dutasteride Evolugen	dutasteride	0.5 mg	capsule, soft	oral use
France	Krka, D.D., Novo Mesto	Dutasteride Krka	dutasteride	0.5 mg	capsule, soft	oral use
France	Krka, D.D., Novo Mesto	Dutasteride Krka	dutasteride	0.5 mg	capsule, soft	oral use
France	Laboratoire Glaxosmithkline	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
France	Laboratoire Glaxosmithkline	Combodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
France	Laboratoires Alter	Finasteride Alter	finasteride	5 mg	film-coated tablet	oral use
France	Laboratoires Bailleul S.A.	Finasteride Bailleul	finasteride	1 mg	film-coated tablet	oral use
France	Mylan S.A.S.	Dutasteride Mylan Generiques	dutasteride	0.5 mg	capsule, soft	oral use
France	Organon France	Propecia	finasteride	1 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
France	Organon France	Chibro-Proscar	finasteride	5 mg	film-coated tablet	oral use
France	Sandoz	Dutasteride/ Tamsulosine Sandoz	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
France	Sandoz	Finasteride Sandoz	finasteride	5 mg	film-coated tablet	oral use
France	Sandoz	Finasteride Sandoz	finasteride	1 mg	film-coated tablet	oral use
France	Sandoz	Dutasteride Sandoz	dutasteride	0.5 mg	capsule, soft	oral use
France	Teva Santé	Finasteride Teva	finasteride	5 mg	film-coated tablet	oral use
France	Teva Santé	Finasteride Teva	finasteride	1 mg	film-coated tablet	oral use
France	Teva Santé	Dutasteride Teva	dutasteride	0.5 mg	capsule, soft	oral use
France	Viartis Sante	Finasteride Viartis	finasteride	5 mg	film-coated tablet	oral use
France	Viartis Sante	Finasteride Viartis	finasteride	1 mg	film-coated tablet	oral use
France	Viartis Sante	Dutasteride Viartis	dutasteride	0.5 mg	capsule, soft	oral use
France	Viartis Sante	Dutasteride/ Tamsulosine Viartis	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
France	Zentiva France	Finasteride Zentiva	finasteride	5 mg	film-coated tablet	oral use
France	Zentiva France	Finasteride Zentiva	finasteride	1 mg	film-coated tablet	oral use
France	Zentiva France	Dutasteride Zentiva Lab	dutasteride	0.5 mg	capsule, soft	oral use
France	Zentiva France	Dutasteride/ Tamsulosine Zentiva	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
France	Zydus France	Finasteride Zydus	finasteride	5 mg	film-coated tablet	oral use
Germany	1 A Pharma Gmbh	Dutacomp	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	1 A Pharma Gmbh	Finasterid 1 A Pharma	finasteride	5 mg	film-coated tablet	oral use
Germany	1 A Pharma Gmbh	Finasterid 1 A Pharma	finasteride	1 mg	film-coated tablet	oral use
Germany	Abanta Pharma Gmbh	Finasterid Uropharm	finasteride	5 mg	film-coated tablet	oral use
Germany	Abanta Pharma Gmbh	Dutasterid/ Tamsulosin Uropharm	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	Accord Healthcare B.V.	Dutasterid/ Tamsulosin Accord	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	Aliud Pharma Gmbh	Finasterid Al	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Germany	Aliud Pharma Gmbh	Finasterid AI	finasteride	1 mg	film-coated tablet	oral use
Germany	Aliud Pharma Gmbh	Dutasterid/ Tamsulosin AI	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	Amarox Pharma Gmbh	Finasterid Amarox	finasteride	5 mg	film-coated tablet	oral use
Germany	Amarox Pharma Gmbh	Finasterid Amarox	finasteride	1 mg	film-coated tablet	oral use
Germany	Apogepha Arzneimittel Gmbh	Prospan	finasteride	5 mg	film-coated tablet	oral use
Germany	Aristo Pharma Gmbh	Finasterid Zur Anwendung Bei Männlichen Patienten Aristo	finasteride	5 mg	film-coated tablet	oral use
Germany	Aristo Pharma Gmbh	Finasterid Aristo	finasteride	5 mg	film-coated tablet	oral use
Germany	Aristo Pharma Gmbh	Finaristo	finasteride	1 mg	film-coated tablet	oral use
Germany	Aristo Pharma Gmbh	Dutasterid Aristo	dutasteride	0.5 mg	capsule, soft	oral use
Germany	Aristo Pharma Gmbh	Dutalosin	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	Ascend Gmbh	Finasterid Ascend	finasteride	5 mg	film-coated tablet	oral use
Germany	Axunio Pharma Gmbh	Finasterid Nio	finasteride	1 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Germany	Betapharm Arzneimittel Gmbh	Dutasterid/ Tamsulosin Beta	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	Biomo Pharma Gmbh	Finasterid Biomo	finasteride	5 mg	film-coated tablet	oral use
Germany	Biomo Pharma Gmbh	Finasterid Biomo	finasteride	1 mg	film-coated tablet	oral use
Germany	Bluefish Pharmaceuticals Ab	Finasterid Bluefish	finasteride	5 mg	film-coated tablet	oral use
Germany	Careforsons Ireland Limited	Finasterid Careforsons	finasteride	1 mg	film-coated tablet	oral use
Germany	Dermapharm Ag	Finapil	finasteride	1 mg	film-coated tablet	oral use
Germany	Dexcel Pharma Gmbh	Finasterid Dexcel	finasteride	1 mg	film-coated tablet	oral use
Germany	Dr. Pflieger Arzneimittel Gmbh	Finural	finasteride	5 mg	film-coated tablet	oral use
Germany	Dr. Pflieger Arzneimittel Gmbh	Tamsublock Duo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	FD Pharma Gmbh	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Germany	Glaxosmithkline Gmbh & Co. Kg	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Germany	Glaxosmithkline Gmbh & Co. Kg	Dutasterid- Tamsulosinhydrochlorid Glaxosmithkline	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Germany	Glaxosmithkline Gmbh & Co. Kg	Duodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	Glenmark Arzneimittel Gmbh	Dutasterid/ Tamsulosin Glenmark	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	Heumann Pharma Gmbh & Co. Generica Kg	Finasterid Zur Anwendung Bei Männlichen Patienten Heumann	finasteride	5 mg	film-coated tablet	oral use
Germany	Heumann Pharma Gmbh & Co. Generica Kg	Finasterid Heumann	finasteride	1 mg	film-coated tablet	oral use
Germany	Heumann Pharma Gmbh & Co. Generica Kg	Dutasterid/ Tamsulosin Heumann	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	Hexal Ag	Finahair	finasteride	1 mg	film-coated tablet	oral use
Germany	Holsten Pharma Gmbh	Finasterid Rivopharm	finasteride	1 mg	film-coated tablet	oral use
Germany	Holsten Pharma Gmbh	Finasterid Ratiopharm	finasteride	5 mg	film-coated tablet	oral use
Germany	Holsten Pharma Gmbh	Finasterid Holsten	finasteride	5 mg	film-coated tablet	oral use
Germany	Holsten Pharma Gmbh	Finasterid Holsten	finasteride	1 mg	film-coated tablet	oral use
Germany	Holsten Pharma Gmbh	Finasterid Abz	finasteride	5 mg	film-coated tablet	oral use
Germany	Holsten Pharma Gmbh	Capila	finasteride	1 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Germany	Hormosan Pharma Gmbh	Finasterid Hormosan	finasteride	1 mg	film-coated tablet	oral use
Germany	Medical Valley Invest Ab	Dutasterid Axiomed	dutasteride	0.5 mg	capsule, soft	oral use
Germany	Medical Valley Invest Ab	Duta-Tamsaxiro	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	Medicopharm Ag	Finasterid Medicopharm	finasteride	5 mg	film-coated tablet	oral use
Germany	Mibe Gmbh Arzneimittel	Finamed Zur Anwendung Bei Männlichen Patienten	finasteride	5 mg	film-coated tablet	oral use
Germany	Mylan Germany Gmbh	Dutasterid/ Tamsulosin Mylan	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	Organon healthcare Gmbh	Proscar Zur Anwendung Bei Männlichen Patienten	finasteride	5 mg	film-coated tablet	oral use
Germany	Organon healthcare Gmbh	Propecia	finasteride	1 mg	film-coated tablet	oral use
Germany	Puren Pharma Gmbh & Co. Kg	Finasterid Puren	finasteride	5 mg	film-coated tablet	oral use
Germany	Puren Pharma Gmbh & Co. Kg	Finasterid Aurobindo	finasteride	5 mg	film-coated tablet	oral use
Germany	Puren Pharma Gmbh & Co. Kg	Finasterid Aurobindo	finasteride	1 mg	film-coated tablet	oral use
Germany	Puren Pharma Gmbh & Co. Kg	Finapuren	finasteride	1 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Germany	Puren Pharma Gmbh & Co. Kg	Dutasterid/ Tamsulosin Puren	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	Ratiopharm Gmbh	Dutasterid/ Tamsulosin Ratiopharm	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	Stadapharm Gmbh	Finasterid Stada	finasteride	5 mg	film-coated tablet	oral use
Germany	Stadapharm Gmbh	Finasterid Stada	finasteride	1 mg	film-coated tablet	oral use
Germany	Tad Pharma Gmbh	Finascar Zur Anwendung Bei Männlichen Erwachsenen	finasteride	5 mg	film-coated tablet	oral use
Germany	Tad Pharma Gmbh	Dutascar	dutasteride	0.5 mg	capsule, soft	oral use
Germany	Tad Pharma Gmbh	Dutastam	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Germany	Winthrop Arzneimittel Gmbh	Finasterid Winthrop	finasteride	5 mg	film-coated tablet	oral use
Germany	Zentiva Pharma Gmbh	Dutasterid- Tamsulosin Zentiva	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Greece	Bennett Pharmaceuticals Sa	Fisterid	finasteride	5 mg	film-coated tablet	oral use
Greece	Demo Abee	Zytodur	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Greece	Demo Abee	Dastidem	dutasteride	0.5 mg	capsule, soft	oral use
Greece	Elpen Pharmaceutical Co. Inc.	Dinaplex	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Greece	Geneparm S.A.	Finastir	finasteride	5 mg	film-coated tablet	oral use
Greece	Geneparm S.A.	Doxared	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Greece	Glaxosmithkline Single Member A.E.B.E.	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Greece	Glaxosmithkline Single Member A.E.B.E.	Duodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Greece	Laboratoires Bailleul S.A.	Andropecia	finasteride	1 mg	film-coated tablet	oral use
Greece	Lavipharm S.A	Prostatyl	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Greece	Libytec Pharmaceutical S.A.	Avielid	finasteride	5 mg	film-coated tablet	oral use
Greece	Pharmapath Sa	Finar	finasteride	5 mg	film-coated tablet	oral use
Greece	Pharmathen Investments Group Limited	Προνυρε	finasteride	5 mg	film-coated tablet	oral use
Greece	Rafarm S.A.	Finazil	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Greece	Rafarm S.A.	Rafuster	dutasteride	0.5 mg	capsule, soft	oral use
Greece	Rafarm S.A.	Dyoster	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Greece	Vian S.A.	Glopisine	finasteride	5 mg	film-coated tablet	oral use
Greece	Vian S.A.	Duaride	dutasteride	0.5 mg	capsule, soft	oral use
Greece	Vianex S.A.	Proscar	finasteride	5 mg	film-coated tablet	oral use
Greece	Vianex S.A.	Propecia	finasteride	1 mg	film-coated tablet	oral use
Greece	Viofar Ltd	Alsteride	finasteride	5 mg	film-coated tablet	oral use
Greece	Vocate Φαρμακευτική ΑΕ	Dustezor	dutasteride	0.5 mg	capsule, soft	oral use
Hungary	Actavis Group Ptc Ehf.	Redupros	finasteride	5 mg	film-coated tablet	oral use
Hungary	Bausch Health Ireland Limited	Finanorm	finasteride	5 mg	film-coated tablet	oral use
Hungary	Exeltis Magyarország Kft.	Unisol	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Hungary	G.L. Pharma Gmbh	Aglandin	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Hungary	Gedeon Richter Plc.	Duamild	finasteride, tamsulosin hydrochloride	5 mg, 0.4 mg	film-coated tablet prolonged-release capsule, hard	oral use
Hungary	Gedeon Richter Plc.	Prosterid	finasteride	5 mg	film-coated tablet	oral use
Hungary	Gedeon Richter Plc.	Gelmor	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Hungary	Glaxosmithkline Trading Services Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Hungary	Glaxosmithkline Trading Services Limited	Duodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Hungary	Krka, D.D., Novo Mesto	Finpros	finasteride	5 mg	film-coated tablet	oral use
Hungary	Krka, D.D., Novo Mesto	Tadusta	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Hungary	Pharmacenter Europe Kft.	Finasteride Pharmacenter	finasteride	5 mg	film-coated tablet	oral use
Hungary	Sandoz Hungária Kft	Finasterid Sandoz	finasteride	5 mg	film-coated tablet	oral use
Hungary	Stada Arzneimittel Ag	Dutasteride/ Tamsulosin Stada	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Hungary	Stada Arzneimittel Ag	Dutasteride/ Tamsulosin Stada	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Hungary	Teva B.V	Tamsudil Duo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Hungary	Teva Gyógyszergyár Zrt	Finasterid Teva	finasteride	5 mg	film-coated tablet	oral use
Iceland	Actavis Group Ptc Ehf.	Finól	finasteride	5 mg	film-coated tablet	oral use
Iceland	Alvogen Ehf	Finasteride Alvogen	finasteride	5 mg	film-coated tablet	oral use
Iceland	Alvogen Ehf	Dutasteride Sumar Pharma	dutasteride	0.5 mg	capsule, soft	oral use
Iceland	Alvogen Pharma Trading Europe Eood	Dutasteride Alvogen	dutasteride	0.5 mg	capsule, soft	oral use
Iceland	Glaxosmithkline Pharma A/S	Duodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Iceland	Medical Valley Invest Ab	Finasterida Medical Valley	finasteride	5 mg	film-coated tablet	oral use
Iceland	Medical Valley Invest Ab	Dutasteride Medical Valley	dutasteride	0.5 mg	capsule, soft	oral use
Iceland	Medical Valley Invest Ab	Duta Tamsaxiro	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Iceland	Stada Arzneimittel Ag	Finasterid Stada	finasteride	5 mg	film-coated tablet	oral use
Iceland	Stada Arzneimittel Ag	Finasterid Stada	finasteride	1 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Iceland	Teva B.V	Dutasteride/ Tamsulosin Teva	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Iceland	Zentiva, K.S.	Dutasteride/ Tamsulosin Alvogen	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Iceland	Zentiva, K.S.	Dutaprostam	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Ireland	Accord Healthcare Ireland Limited	Finasteride Accord Healthcare Ireland	finasteride	5 mg	film-coated tablet	oral use
Ireland	Accord Healthcare Ireland Limited	Dutasteride/ Tamsulosin Hydrochloride Accord Healthcare Ireland	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Ireland	Aurobindo Pharma (Malta) Limited	Fintrid	finasteride	5 mg	film-coated tablet	oral use
Ireland	Careforsons Ireland Limited	Finasteride Careforsons Ireland	finasteride	1 mg	film-coated tablet	oral use
Ireland	Glaxosmithkline (Ireland) Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Ireland	Glaxosmithkline (Ireland) Limited	Combodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Ireland	Krka, D.D., Novo Mesto	Dutasteride Krka	dutasteride	0.5 mg	capsule, soft	oral use
Ireland	Mcdermott Laboratories Ltd	Dutasteride/ Tamsulosin Hydrochloride Mylan	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Ireland	Organon Pharma (Ireland) Limited	Proscar	finasteride	5 mg	film-coated tablet	oral use
Ireland	Rowa Pharmaceuticals Limited	Dutasteride Rowa	dutasteride	0.5 mg	capsule, soft	oral use
Ireland	Rowa Pharmaceuticals Limited	Dutasteride/ Tamsulosin Rowa	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Ireland	Teva Pharma B.V.	Dutasteride Teva	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Abc Farmaceutici S.P.A.	Finasteride Abc	finasteride	5 mg	film-coated tablet	oral use
Italy	Accord Healthcare S.L.U.	Finasteride Ahcl	finasteride	5 mg	film-coated tablet	oral use
Italy	Accord Healthcare S.L.U.	Finasteride Ahcl	finasteride	1 mg	film-coated tablet	oral use
Italy	Accord Healthcare S.L.U.	Dutasteride Accord	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Alfasigma S.P.A.	Prostide	finasteride	5 mg	film-coated tablet	oral use
Italy	Alfasigma S.P.A.	Ormicton	finasteride	5 mg	film-coated tablet	oral use
Italy	Almus S.R.L.	Finasteride Almus	finasteride	5 mg	film-coated tablet	oral use
Italy	Amarox Pharma GmbH	Finasteride AmaroX	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Italy	Amarox Pharma Gmbh	Finasteride AmaroX	finasteride	1 mg	film-coated tablet	oral use
Italy	Aristo Pharma Gmbh	Dutasteride Aristo	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Aristo Pharma Gmbh	Dutasteride E Tamsulosina Aristo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Italy	Aurobindo Pharma (Italia) S.R.L.	Finasteride Aurobindo Pharma Italia	finasteride	1 mg	film-coated tablet	oral use
Italy	Aurobindo Pharma (Italia) S.R.L.	Finasteride Aurobindo	finasteride	5 mg	film-coated tablet	oral use
Italy	Aurobindo Pharma (Italia) S.R.L.	Dutasteride Aurobindo	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Bruno Farmaceutici	Fixad	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Italy	Difa Cooper S.P.A.	Carefinast	finasteride	1 mg	film-coated tablet	oral use
Italy	Doc Generici S.R.L.	Finasteride Doc	finasteride	5 mg	film-coated tablet	oral use
Italy	Doc Generici S.R.L.	Dutasteride Doc Generici	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Ecupharma S.R.L.	Decuster	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Eg S.P.A.	Sitas	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Italy	Eg S.P.A.	Finasteride Eg Stada	finasteride	1 mg	film-coated tablet	oral use
Italy	Eg S.P.A.	Finasteride Eg	finasteride	5 mg	film-coated tablet	oral use
Italy	Eg S.P.A.	Dutasteride Eg	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Epifarma S.R.L.	Asterid	finasteride	5 mg	film-coated tablet	oral use
Italy	Farma Group S.R.L.	Produtal	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Farmitalia S.R.L.	Anasso	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Italy	G.L. Invest S.R.L.S	Finestar	finasteride	5 mg	film-coated tablet	oral use
Italy	Genetic Spa	Stecur	finasteride	5 mg	film-coated tablet	oral use
Italy	Giuliani Spa	Finacapil	finasteride	1 mg	film-coated tablet	oral use
Italy	Glaxosmithkline S.P.A.	Duagen	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Glaxosmithkline S.P.A.	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Glaxosmithkline S.P.A.	Jelnu	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Italy	Glaxosmithkline S.P.A.	Combodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Italy	I.B.N. Savio S.R.L.	Prodirexan	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Ipsos Pharma S.R.L.	Finasteride Ipsos Pharma	finasteride	5 mg	film-coated tablet	oral use
Italy	Krka, D.D., Novo Mesto	Dutasteride Krka	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Krka, D.D., Novo Mesto	Dutasteride Krka	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Laboratoires Bailleul S.A.	Finasteride Biorga	finasteride	1 mg	film-coated tablet	oral use
Italy	Laboratori Alter S.R.L.	Finasteride Alter	finasteride	5 mg	film-coated tablet	oral use
Italy	Laboratori Alter S.R.L.	Dutasteride Alter	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Lanova Farmaceutici S.R.L.	Finedor	finasteride	5 mg	film-coated tablet	oral use
Italy	Mylan S.P.A.	Finasteride Mylan Italia	finasteride	5 mg	film-coated tablet	oral use
Italy	Mylan S.P.A.	Finasteride Mylan Generics Italia	finasteride	1 mg	film-coated tablet	oral use
Italy	Mylan S.P.A.	Dutasteride Mylan	dutasteride	0.5 mg	capsule, soft	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Italy	Neopharmed Gentili Spa	Genaprost	finasteride	5 mg	film-coated tablet	oral use
Italy	Neopharmed Gentili Spa	Finastid	finasteride	5 mg	film-coated tablet	oral use
Italy	Neopharmed Gentili Spa	Olanix	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Italy	Organon Italia S.R.L.	Proscar	finasteride	5 mg	film-coated tablet	oral use
Italy	Organon Italia S.R.L.	Propecia	finasteride	1 mg	film-coated tablet	oral use
Italy	Pharmacare Srl	Filasel	finasteride	1 mg	film-coated tablet	oral use
Italy	Pharmacare Srl	Fendazel	finasteride	1 mg	film-coated tablet	oral use
Italy	Pharmacare Srl	Dutas	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Pharmacare Srl	Terip	finasteride	5 mg	film-coated tablet	oral use
Italy	Pharmacare Srl	Durital	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Pharmacare Srl	Duttam	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Italy	S&R Farmaceutici	Produxen	dutasteride	0.5 mg	capsule, soft	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Italy	S.F. Group Srl	Ridestin	finasteride	5 mg	film-coated tablet	oral use
Italy	S.F. Group Srl	Vivister	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Sandoz Gmbh	Dutasteride Sandoz Gmbh	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Sandoz S.P.A.	Finasteride Sandoz	finasteride	5 mg	film-coated tablet	oral use
Italy	Strides Pharma (Cyprus) Limited	Dutasteride Strides	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Sun Pharmaceutical Industries Europe B.V.	Finasteride Sun Pharma Italia Srl	finasteride	5 mg	film-coated tablet	oral use
Italy	Sun Pharmaceutical Industries Europe B.V.	Finasteride Ranbaxy	finasteride	5 mg	film-coated tablet	oral use
Italy	Tecnigen S.R.L.	Dutasteride Tecnigen	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Tecnimede - Sociedade Técnico-Medicinal, Sa	Finasteride Tecnigen	finasteride	5 mg	film-coated tablet	oral use
Italy	Teva Italia S.R.L.	Finasteride Teva Italia	finasteride	5 mg	film-coated tablet	oral use
Italy	Teva Italia S.R.L.	Finasteride Teva Generics	finasteride	1 mg	film-coated tablet	oral use
Italy	Teva Italia S.R.L.	Dutasteride Teva	dutasteride	0.5 mg	capsule, soft	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Italy	Towa Pharmaceutical S.P.A.	Finasteride Pensa	finasteride	5 mg	film-coated tablet	oral use
Italy	Towa Pharmaceutical S.P.A.	Finasteride Pensa	finasteride	1 mg	film-coated tablet	oral use
Italy	Towa Pharmaceutical S.P.A.	Dutasteride Pensa	dutasteride	0.5 mg	capsule, soft	oral use
Italy	Towa Pharmaceutical S.P.A.	Dutasteride E Tamsulosina Pensa	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Italy	Zentiva Italia S.R.L.	Finasteride Zentiva	finasteride	5 mg	film-coated tablet	oral use
Italy	Zentiva Italia S.R.L.	Dutasteride Zentiva	dutasteride	0.5 mg	capsule, soft	oral use
Latvia	Accord Healthcare B.V.	Finasteride Accord	finasteride	5 mg	film-coated tablet	oral use
Latvia	Accord Healthcare B.V.	Finasteride Accord	finasteride	1 mg	film-coated tablet	oral use
Latvia	Glaxosmithkline (Ireland) Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Latvia	Glaxosmithkline Trading Services Limited	Combodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Latvia	JSC Olainfarm	Dutasteride/ Tamsulosin Olainfarm	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Latvia	Krka, D.D., Novo Mesto	Dutrys	dutasteride	0.5 mg	capsule, soft	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Latvia	Krka, D.D., Novo Mesto	Tadustix	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Latvia	Sia Elvim	Dutasteride Elvim	dutasteride	0.5 mg	capsule, soft	oral use
Latvia	Teva B.V	Dutasteride/ Tamsulosin Teva	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Latvia	Teva Pharma B.V.	Finasteride Teva	finasteride	5 mg	film-coated tablet	oral use
Latvia	Teva Pharma B.V.	Dutasteride Teva	dutasteride	0.5 mg	capsule, soft	oral use
Latvia	Viartis Limited	Dutasteride/ Tamsulosin Viartis	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Latvia	Zentiva, K.S.	Penester	finasteride	5 mg	film-coated tablet	oral use
Latvia	Zentiva, K.S.	Dutrozen	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Lithuania	Accord Healthcare B.V.	Finasteride Accord	finasteride	5 mg	film-coated tablet	oral use
Lithuania	Glaxosmithkline (Ireland) Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Lithuania	Glaxosmithkline Trading Services Limited	Combodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Lithuania	JSC Olainfarm	Dutasteride / Tamsulosin Olainfarm	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Lithuania	Krka, D.D., Novo Mesto	Dortilla	dutasteride	0.5 mg	capsule, soft	oral use
Lithuania	Krka, D.D., Novo Mesto	Dutasteride/ Tamsulosin Krka	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Lithuania	Sandoz Pharmaceuticals D.D.	Aduzin	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Lithuania	Sia Elvim	Dutasteride Elvim	dutasteride	0.5 mg	capsule, soft	oral use
Lithuania	Teva Pharma B.V.	Finasteride Teva	finasteride	5 mg	film-coated tablet	oral use
Lithuania	Teva Pharma B.V.	Dutasteride Teva	dutasteride	0.5 mg	capsule, soft	oral use
Lithuania	Viartis Limited	Dutasteride/ Tamsulosin Viartis	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Lithuania	Zentiva, K.S.	Penester	finasteride	5 mg	film-coated tablet	oral use
Lithuania	Zentiva, K.S.	Dutrozen	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Luxembourg	Eurogenerics N.V./S.A.	Finasteride Eg	finasteride	5 mg	film-coated tablet	oral use
Luxembourg	Eurogenerics N.V./S.A.	Dutasteride/ Tamsulosine Eg	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Luxembourg	Glaxosmithkline Pharmaceuticals En Abrege Glaxosmithkline	Avodart	dutasteride	0.5 mg	capsule, soft	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Luxembourg	Glaxosmithkline Pharmaceuticals En Abrege Glaxosmithkline	Combodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Luxembourg	Laboratoires Bailleul S.A.	Finasteride Bailleul	finasteride	1 mg	film-coated tablet	oral use
Luxembourg	Organon Belgium	Proscar	finasteride	5 mg	film-coated tablet	oral use
Luxembourg	Organon Belgium	Propecia	finasteride	1 mg	film-coated tablet	oral use
Luxembourg	Ratiopharm Gmbh	Dutasterid/ Tamsulosin Ratiopharm	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Luxembourg	Viartis Gx	Dutasteride/ Tamsulosine Viartis	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Malta	Abanta Pharma Gmbh	Dutasterid/ Tamsulosin Uropharm	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Malta	Accord Healthcare Ireland Limited	Dutasteride/ Tamsulosin Hydrochloride Accord Healthcare Ireland	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Malta	Ascend Gmbh	Finasteride Ascend	finasteride	5 mg	film-coated tablet	oral use
Malta	Aurobindo Pharma (Malta) Limited	Finasteride Aurobindo Pharma (Malta)	finasteride	1 mg	film-coated tablet	oral use
Malta	Aurobindo Pharma (Malta) Limited	Finasteride Aurobindo	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Malta	Biogaran	Dutasteride/ Tamsulosin Biogaran	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Malta	Doc Generici S.R.L.	Dutasteride Doc Generici	dutasteride	0.5 mg	capsule, soft	oral use
Malta	G.L. Pharma Gmbh	Dutalan	dutasteride	0.5 mg	capsule, soft	oral use
Malta	Galenicum Health, S.L.	Dutasteride Galenicum	dutasteride	0.5 mg	capsule, soft	oral use
Malta	Galenicum Health, S.L.	Dutasteride Galenicum	dutasteride	0.5 mg	capsule, soft	oral use
Malta	Galenicum Health, S.L.	Dutasteride/ Tamsulosin Galenicum Health	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Malta	Galenicum Health, S.L.	Dutasteride/ Tamsulosin Diagonalis	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Malta	Galenicum Health, S.L.	Dutamin	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Malta	Genepharm S.A.	Dutasteride / Tamsulosin Genepharm	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Malta	Glaxosmithkline (Ireland) Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Malta	Glaxosmithkline (Ireland) Limited	Combodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Malta	Gp-Pharm S.A.	Duplotrip	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Malta	Heaton K.S.	Atucare	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Malta	Laboratoires Bailleul S.A.	Finasteride Biorga	finasteride	1 mg	film-coated tablet	oral use
Malta	Lavipharm S.A	Prostatyl	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Malta	Mylan Ireland Limited	Dutasteride Mylan	dutasteride	0.5 mg	capsule, soft	oral use
Malta	N.V. Organon	Propecia	finasteride	1 mg	film-coated tablet	oral use
Malta	Rafarm S.A.	Dyoster	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Malta	Viartis Limited	Dutapro Mylan	dutasteride	0.5 mg	capsule, soft	oral use
Netherlands	Accord Healthcare B.V.	Finasteride Accord	finasteride	5 mg	film-coated tablet	oral use
Netherlands	Accord Healthcare B.V.	Finasteride Accord	finasteride	1 mg	film-coated tablet	oral use
Netherlands	Accord Healthcare B.V.	Dutasteride Accord	dutasteride	0.5 mg	capsule, soft	oral use
Netherlands	Aet, De	Finasteride Tiefenbacher	finasteride	5 mg	film-coated tablet	oral use
Netherlands	Amarox Pharma B.V.	Finasteride Amarox	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Netherlands	Aristo Pharma Gmbh	Finasteride Aristo	finasteride	5 mg	film-coated tablet	oral use
Netherlands	Aurobindo Pharma B.V.	Finasteride Aurobindo	finasteride	5 mg	film-coated tablet	oral use
Netherlands	Aurobindo Pharma B.V.	Finasteride Aurobindo	finasteride	1 mg	film-coated tablet	oral use
Netherlands	Aurobindo Pharma B.V.	Dutasteride Aurobindo	dutasteride	0.5 mg	capsule, soft	oral use
Netherlands	Aurobindo Pharma B.V.	Dutasteride/ Tamsulosinehydrochloride Aurobindo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Netherlands	Focus Care Pharmaceuticals B.V.	Dutasteride/ Tamsulosine Hcl Focus Care Pharmaceuticals	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Netherlands	Glaxosmithkline B.V.	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Netherlands	Glaxosmithkline B.V.	Combodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Netherlands	Medical Valley Invest Ab	Dutasteride Xiromed	dutasteride	0.5 mg	capsule, soft	oral use
Netherlands	Medical Valley Invest Ab	Dutasteride/ Tamsulosin Hcl Xiromed	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Netherlands	N.V. Organon	Proscar	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Netherlands	N.V. Organon	Propecia	finasteride	1 mg	film-coated tablet	oral use
Netherlands	Sandoz B.V.	Dutasteride/ Tamsulosine Hcl Sandoz	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Netherlands	Sandoz B.V.	Dutasteride Sandoz	dutasteride	0.5 mg	capsule, soft	oral use
Netherlands	Strides Pharma (Cyprus) Limited	Dutasteride Strides	dutasteride	0.5 mg	capsule, soft	oral use
Netherlands	Teva B.V	Dutasteride/ Tamsulosinehydrochl oride Teva	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Netherlands	Teva Nederland B.V.	Finasteride Teva	finasteride	5 mg	film-coated tablet	oral use
Netherlands	Teva Nederland B.V.	Finasteride Teva	finasteride	1 mg	film-coated tablet	oral use
Netherlands	Teva Nederland B.V.	Dutasteride Teva	dutasteride	0.5 mg	capsule, soft	oral use
Netherlands	Viatriis Limited	Finasteride Viatriis	finasteride	1 mg	film-coated tablet	oral use
Netherlands	Viatriis Limited	Dutasteride/ Tamsulosine Hcl Viatriis	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Norway	2care4 Generics Aps	Prosterid	finasteride	1 mg	film-coated tablet	oral use
Norway	Actavis Group Ptc Ehf.	Finasterid Actavis	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Norway	Glaxosmithkline As	Duodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Norway	Hexal A/S	Dutasteride/ Tamsulosin Hexal	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Norway	Laboratorios León Farma, S.A.	Dutasteride León Farma	dutasteride	0.5 mg	capsule, soft	oral use
Norway	Medical Valley Invest Ab	Dutasteride Medical Valley	dutasteride	0.5 mg	capsule, soft	oral use
Norway	Medical Valley Invest Ab	Dutasteride/ Tamsulosin Medical Valley	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Norway	N.V. Organon	Proscar	finasteride	5 mg	film-coated tablet	oral use
Norway	Orion Corporation	Dutasteride/ Tamsulosin Orion	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Norway	Teva B.V	Dutasterid/ Tamsulosin Teva	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Norway	Viatriis Limited	Dutasteride/ Tamsulosin Viatriis	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Poland	+pharma Arzneimittel Gmbh	Hyplafin	finasteride	5 mg	film-coated tablet	oral use
Poland	+pharma Arzneimittel Gmbh	Dutafin	dutasteride	0.5 mg	capsule, soft	oral use
Poland	+pharma Arzneimittel Gmbh	Duitam	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Poland	Accord Healthcare Polska Sp. Z O.O.	Finahit	finasteride	5 mg	film-coated tablet	oral use
Poland	Accord Healthcare Polska Sp. Z O.O.	Finahit	finasteride	1 mg	film-coated tablet	oral use
Poland	Actavis Group Ptc Ehf.	Androster	finasteride	5 mg	film-coated tablet	oral use
Poland	Adamed Pharma S.A.	Adaster	finasteride	5 mg	film-coated tablet	oral use
Poland	Adamed Pharma S.A.	Adadut	dutasteride	0.5 mg	capsule, soft	oral use
Poland	Adamed Pharma S.A.	Adatam Duo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Poland	Aristo Pharma Sp. Z O.O.	Uronezyr	finasteride	5 mg	film-coated tablet	oral use
Poland	Aristo Pharma Sp. Z O.O.	Nezyr	finasteride	1 mg	film-coated tablet	oral use
Poland	Aristo Pharma Sp. Z O.O.	Dutazyr	dutasteride	0.5 mg	capsule, soft	oral use
Poland	Aristo Pharma Sp. Z O.O.	Marumax	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Poland	Aurovitas Pharma Polska Sp. Z O.O.	Apo-Fina	finasteride	5 mg	film-coated tablet	oral use
Poland	Aurovitas Pharma Polska Sp. Z O.O.	Findarts	dutasteride	0.5 mg	capsule, soft	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Poland	Aurovitas Pharma Polska Sp. Z O.O	Findarts Duo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Poland	Bluefish Pharmaceuticals Ab	Finasteridum Bluefish	finasteride	5 mg	film-coated tablet	oral use
Poland	G.L. Pharma Gmbh	Geroladut	dutasteride	0.5 mg	capsule, soft	oral use
Poland	G.L. Pharma Gmbh	Landulosin	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Poland	Gedeon Richter Plc.	Zasterid	finasteride	5 mg	film-coated tablet	oral use
Poland	Glaxosmithkline (Ireland) Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Poland	Glaxosmithkline (Ireland) Limited	Duodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Poland	Krka, D.D., Novo Mesto	Finpros	finasteride	5 mg	film-coated tablet	oral use
Poland	Krka, D.D., Novo Mesto	Dutrys	dutasteride	0.5 mg	capsule, soft	oral use
Poland	Krka, D.D., Novo Mesto	Twinpros	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Poland	Laboratorios León Farma, S.A.	Dutasteride + Tamsulosin Hydrochloride León Farma	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Poland	Medreg S.R.O.	Finasteride Medreg	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Poland	Organon Polska Sp. Z O.O.	Proscar	finasteride	5 mg	film-coated tablet	oral use
Poland	Organon Polska Sp. Z O.O.	Propecia	finasteride	1 mg	film-coated tablet	oral use
Poland	Orion Corporation	Antiprost	finasteride	5 mg	film-coated tablet	oral use
Poland	Przedsiębiorstwo Farmaceutyczne Lek-Am Sp. Z O.O.	Finaster	finasteride	5 mg	film-coated tablet	oral use
Poland	Przedsiębiorstwo Farmaceutyczne Lek-Am Sp. Z O.O.	Androstatin	finasteride	1 mg	film-coated tablet	oral use
Poland	Ranbaxy Poland Sp. Zo.O	Finaran	finasteride	5 mg	film-coated tablet	oral use
Poland	Recordati Polska Sp. Z O.O.	Finxta	finasteride	5 mg	film-coated tablet	oral use
Poland	Sun-Farm Sp. Z.O.O.	Finapil	finasteride	1 mg	film-coated tablet	oral use
Poland	Symphar Sp. Z O.O.	Symasteride	finasteride	5 mg	film-coated tablet	oral use
Poland	Symphar Sp. Z O.O.	Finasteride Symphar	finasteride	5 mg	film-coated tablet	oral use
Poland	Synthaverse S.A.	Davoster	dutasteride	0.5 mg	capsule, soft	oral use
Poland	Teva Pharmaceuticals Polska Sp. Z O.O.	Finamef	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Poland	Zentiva, K.S.	Penester	finasteride	5 mg	film-coated tablet	oral use
Poland	Zentiva, K.S.	Dutrozen	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Accord Healthcare S.L.U.	Finasterida Accord	finasteride	5 mg	film-coated tablet	oral use
Portugal	Accord Healthcare S.L.U.	Dutasterida + Tansulosina Accord	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, soft	oral use
Portugal	Alter Genéricos - Comercialização De Produtos Genéricos Lda.	Dutasterida + Tansulosina Alter Genéricos	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, soft	oral use
Portugal	Alter S.A.	Finasterida Alter	finasteride	5 mg	film-coated tablet	oral use
Portugal	Alter S.A.	Neomyx	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Amarox Pharma Gmbh	Finasterida Amarox	finasteride	5 mg	film-coated tablet	oral use
Portugal	Amarox Pharma Gmbh	Finasterida Amarox	finasteride	1 mg	film-coated tablet	oral use
Portugal	Aristo Pharma Gmbh	Finasterida Aristo	finasteride	5 mg	film-coated tablet	oral use
Portugal	Aristo Pharma Gmbh	Dutasterida + Tansulosina Aristo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Bluefish Pharmaceuticals Ab	Finasterida Bluefish	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Portugal	Bluefish Pharmaceuticals Ab	Finasterida Bluefish	finasteride	1 mg	film-coated tablet	oral use
Portugal	Bluepharma Genéricos - Comércio De Medicamentos, S.A.	Finasterida Bluepharma	finasteride	1 mg	film-coated tablet	oral use
Portugal	Bluepharma Genéricos - Comércio De Medicamentos, S.A.	Finasterida Bluepharma	finasteride	5 mg	coated tablet	oral use
Portugal	Bluepharma Genéricos - Comércio De Medicamentos, S.A.	Dutasterida Bluesar	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Bluepharma Genéricos - Comércio De Medicamentos, S.A.	Dutasterida Bluepharma	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Bluepharma Genéricos - Comércio De Medicamentos, S.A.	Dutasterida + Tansulosina Bluepharma	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Bradex S.A.	Dutasterida Bradex	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Ciclum Farma Unipessoal Lda.	Finasterida Ciclum	finasteride	5 mg	film-coated tablet	oral use
Portugal	Ciclum Farma Unipessoal Lda.	Dutasterida Ciclum	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Ciclum Farma Unipessoal Lda.	Dutasterida + Tansulosina Ciclum	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Ciclum Farma Unipessoal Lda.	Dutasterida + Tansulosina Ciclum	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Portugal	Dna Pharma, Lda	Finasterida	finasteride	5 mg	film-coated tablet	oral use
Portugal	Dna Pharma, Lda	Finasterida	finasteride	5 mg	film-coated tablet	oral use
Portugal	Dna Pharma, Lda	Finasterida	finasteride	1 mg	film-coated tablet	oral use
Portugal	Exeltis Healthcare S.L	Unisol	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Exeltis Healthcare S.L	Unisol	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Faes Farma Portugal, S.A.	Finasterida Vitória	finasteride	5 mg	film-coated tablet	oral use
Portugal	Farma 1000 - Produtos Farmacêuticos, Lda.	Finasterida Tecnilor	finasteride	5 mg	film-coated tablet	oral use
Portugal	Farmoz - Sociedade Técnico Medicinal, S.A.	Finasterida Farmoz	finasteride	5 mg	film-coated tablet	oral use
Portugal	Farmoz - Sociedade Técnico Medicinal, S.A.	Dutasterida Farmoz	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Farmoz - Sociedade Técnico Medicinal, S.A.	Dutasterida + Tansulosina Farmoz	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Generis Farmacêutica, S.A.	Finasterida Ritisca	finasteride	5 mg	film-coated tablet	oral use
Portugal	Generis Farmacêutica, S.A.	Finasterida Labesfal	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Portugal	Generis Farmacêutica, S.A.	Finasterida Generis	finasteride	5 mg	film-coated tablet	oral use
Portugal	Generis Farmacêutica, S.A.	Dutasterida Aurovitas	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Generis Farmacêutica, S.A.	Dutasterida + Tansulosina Generis Phar	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Generis Farmacêutica, S.A.	Dutasterida + Tansulosina Generis	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Generis Farmacêutica, S.A.	Dutasterida + Tansulosina Aurovitas	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Generis Phar, Unipessoal Lda.	Finasterida Generis Phar	finasteride	1 mg	film-coated tablet	oral use
Portugal	Glaxo Wellcome Farmacêutica, Lda	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Glaxo Wellcome Farmacêutica, Lda	Combodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Glaxosmithkline - Produtos Farmaceuticos, Lda	Duagen	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Glaxosmithkline - Produtos Farmaceuticos, Lda	Juteo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	GP – Genéricos Portugueses, Lda.	Finasterida GP	finasteride	5 mg	film-coated tablet	oral use
Portugal	Krka, D.D., Novo Mesto	Dutasterida Krka	dutasteride	0.5 mg	capsule, soft	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Portugal	Laboratoires Bailleul S.A.	Finasterida Biorga	finasteride	1 mg	film-coated tablet	oral use
Portugal	Laboratorios Salvat, S.A.	Ilmago	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Laboratório Edol - Produtos Farmacêuticos, S.A.	Hedox	finasteride	1 mg	film-coated tablet	oral use
Portugal	Laboratórios Atral, S.A.	Finasterida Atral	finasteride	5 mg	coated tablet	oral use
Portugal	Laboratórios Atral, S.A.	Sarix	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A.	Finasterida Azevedos	finasteride	5 mg	film-coated tablet	oral use
Portugal	Lifewell - Pharmaceutical & Healthcare, Lda.	Redict	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Mylan Lda.	Finasterida Mylan	finasteride	5 mg	film-coated tablet	oral use
Portugal	Mylan Lda.	Dutasterida Mylan	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Mylan Lda.	Dutasterida + Tansulosina Mylan	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Mylan Lda.	Dutasterida + Tansulosina Mylan	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Organon Portugal, Sociedade Unipessoal Lda.	Proscar	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Portugal	Organon Portugal, Sociedade Unipessoal Lda.	Propecia	finasteride	1 mg	film-coated tablet	oral use
Portugal	Pentafarma - Sociedade Tecnico-Medicinal S.A.	Finasterida Impruve	finasteride	5 mg	film-coated tablet	oral use
Portugal	Pentafarma - Sociedade Tecnico-Medicinal S.A.	Dutasterida Pentafarma	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Pharma Bavaria Internacional (Pbi) Portugal Unipessoal Lda	Aripsa	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Pharmacare Premium Limited	Finasterida Pharmacare	finasteride	5 mg	film-coated tablet	oral use
Portugal	Pharmakern Portugal - Produtos Farmacêuticos, Sociedade Unipessoal, Lda.	Finasterida Pharmakern	finasteride	5 mg	film-coated tablet	oral use
Portugal	Pharmakern Portugal - Produtos Farmacêuticos, Sociedade Unipessoal, Lda.	Finasterida Pharmakern	finasteride	1 mg	film-coated tablet	oral use
Portugal	Pharmakern Portugal - Produtos Farmacêuticos, Sociedade Unipessoal, Lda.	Dutasterida Pharmakern	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Pharmakern Portugal - Produtos Farmacêuticos, Sociedade Unipessoal, Lda.	Dutasterida + Tansulosina Pharmakern	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Pharmakern Portugal - Produtos Farmacêuticos, Sociedade Unipessoal, Lda.	Dutasterida + Tansulosina Betude Pharmakern Portugal - Produtos Farmacêuticos, Sociedade Unipessoal	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Portugal	PLS Pharma, Produtos Farmacêuticos Lda	Finasterida PLS	finasteride	5 mg	film-coated tablet	oral use
Portugal	PLS Pharma, Produtos Farmacêuticos Lda	Finasterida PLS	finasteride	1 mg	film-coated tablet	oral use
Portugal	Rafarm S.A.	Dutasterida Rafarm	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Ratiopharm-Comercio E Industria De Produtos Farmaceuticos Lda	Finasterida Ratiopharm	finasteride	5 mg	film-coated tablet	oral use
Portugal	Ratiopharm-Comercio E Industria De Produtos Farmaceuticos Lda	Finasterida Ratiopharm	finasteride	1 mg	film-coated tablet	oral use
Portugal	Ratiopharm-Comercio E Industria De Produtos Farmaceuticos Lda	Dutasterida Ratiopharm	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Ratiopharm-Comercio E Industria De Produtos Farmaceuticos Lda	Dutasterida + Tansulosina Ratiopharm	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Sandoz Farmacêutica Lda.	Finasterida Sandoz	finasteride	5 mg	film-coated tablet	oral use
Portugal	Sandoz Farmacêutica Lda.	Dutasterida Sandoz	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Tad Pharma Gmbh	Dutasterida + Tansulosina Tad	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Tetrafarma- Produtos Farmacêuticos, Lda.	Finasterida Tetrafarma	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Portugal	Teva B.V	Dutasterida + Tansulosina Teva	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Teva Pharma - Produtos Farmacêuticos Lda	Finasterida Teva	finasteride	5 mg	film-coated tablet	oral use
Portugal	Teva Pharma - Produtos Farmacêuticos Lda	Dutasterida Teva	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Towa Pharmaceutical S.A.	Finasterida Tolife	finasteride	5 mg	coated tablet	oral use
Portugal	Towa Pharmaceutical S.A.	Dutasterida Tolife	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Towa Pharmaceutical S.A.	Dutasterida + Tansulosina Tolife	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Portugal	Zentiva Portugal, Lda	Finasterida Zentiva	finasteride	5 mg	film-coated tablet	oral use
Portugal	Zentiva Portugal, Lda	Dutasterida Zentiva	dutasteride	0.5 mg	capsule, soft	oral use
Portugal	Zentiva Portugal, Lda	Dutasterida + Tansulosina Zentiva	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Romania	Arena Group S.A	Finasterida Arena	finasteride	5 mg	film-coated tablet	oral use
Romania	Cipla Europe Nv	Dutasteridă Cipla	dutasteride	0.5 mg	capsule, soft	oral use
Romania	Glaxosmithkline Trading Services Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Romania	Glaxosmithkline Trading Services Limited	Duodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Romania	Heaton K.S.	Deridust	dutasteride	0.5 mg	capsule, soft	oral use
Romania	Heaton K.S.	Rimril	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Romania	Krka, D.D., Novo Mesto	Dutrys	dutasteride	0.5 mg	capsule, soft	oral use
Romania	Krka, D.D., Novo Mesto	Twinpros	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Romania	Organon Biosciences S.R.L.	Proscar	finasteride	5 mg	film-coated tablet	oral use
Romania	Organon Biosciences S.R.L.	Propecia	finasteride	1 mg	film-coated tablet	oral use
Romania	Stada M&D S.R.L.	Maxtrid	dutasteride	0.5 mg	capsule, soft	oral use
Romania	Stada M&D S.R.L.	Dutasteridă/ Tamsulosin Stada	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Romania	Stada M&D S.R.L.	Dutasteridă / Tamsulosin	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Romania	Terapia S.A.	Asium	dutasteride	0.5 mg	capsule, soft	oral use
Romania	Zentiva, K.S.	Dutasteridă Zentiva	dutasteride	0.5 mg	capsule, soft	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Romania	Zentiva, K.S.	Dutazen	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovakia	Accord Healthcare Polska Sp. Z O.O.	Finasteride Accord	finasteride	5 mg	film-coated tablet	oral use
Slovakia	Accord Healthcare Polska Sp. Z O.O.	Dutasterid Accord	dutasteride	0.5 mg	capsule, soft	oral use
Slovakia	Adamed	Adatam	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovakia	Adamed Pharma S.A.	Adadut	dutasteride	0.5 mg	capsule, soft	oral use
Slovakia	Ardez Pharma	Dutamon	dutasteride	0.5 mg	capsule, soft	oral use
Slovakia	Ardez Pharma	Tedez	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovakia	Bausch Health Ireland Limited	Finanorm	finasteride	5 mg	film-coated tablet	oral use
Slovakia	Belupo D.D.	Belodut	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovakia	Cande S.R.O.	Finamed	finasteride	5 mg	film-coated tablet	oral use
Slovakia	Cande S.R.O.	Dutamed	dutasteride	0.5 mg	capsule, soft	oral use
Slovakia	Cande S.R.O.	Tamed	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Slovakia	Farmak International Sp. Z O.O.	Dutasterid/ Tamsulozín Fmk	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovakia	G.L. Pharma Gmbh	Androfin	finasteride	5 mg	film-coated tablet	oral use
Slovakia	G.L. Pharma Gmbh	Dutalan	dutasteride	0.5 mg	capsule, soft	oral use
Slovakia	G.L. Pharma Gmbh	Aglandin	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovakia	Glaxosmithkline (Ireland) Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Slovakia	Glaxosmithkline Trading Services Limited	Duodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovakia	Glenmark Pharmaceuticals S.R.O.	Dutasteride/ Tamsulosin Glenmark	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovakia	Heaton K.S.	Atucare	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovakia	Krka, D.D., Novo Mesto	Finpros	finasteride	5 mg	film-coated tablet	oral use
Slovakia	Krka, D.D., Novo Mesto	Dutrys	dutasteride	0.5 mg	capsule, soft	oral use
Slovakia	Krka, D.D., Novo Mesto	Dutasteride/ Tamsulosin Krka	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovakia	Viphaarm S.A.	Alkapidan	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Slovakia	Zentiva, K.S.	Penester	finasteride	5 mg	film-coated tablet	oral use
Slovenia	Accord Healthcare Polska Sp. Z O.O.	Dutasterid Accordpharma	dutasteride	0.5 mg	capsule, soft	oral use
Slovenia	Alkaloid-Int D.O.O.	Lestedon	dutasteride	0.5 mg	capsule, soft	oral use
Slovenia	Alkaloid-Int D.O.O.	Tamlos Combo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovenia	Apta Medica Internacional D.O.O.	Amdut	dutasteride	0.5 mg	capsule, soft	oral use
Slovenia	Apta Medica Internacional D.O.O.	Amdut Combo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovenia	Glaxosmithkline Trading Services Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Slovenia	Glaxosmithkline Trading Services Limited	Combodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovenia	Krka, D.D., Novo Mesto	Finpros	finasteride	5 mg	film-coated tablet	oral use
Slovenia	Krka, D.D., Novo Mesto	Dortilla	dutasteride	0.5 mg	capsule, soft	oral use
Slovenia	Krka, D.D., Novo Mesto	Dutamyz	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovenia	Lek Pharmaceuticals D.D. Ljubljana	Miktan Combi	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Slovenia	Lek Pharmaceuticals D.D. Ljubljana	Miktan Combi	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Slovenia	N.V. Organon	Prostide	finasteride	5 mg	film-coated tablet	oral use
Slovenia	N.V. Organon	Propecia	finasteride	1 mg	film-coated tablet	oral use
Spain	Ababor Pharmaceuticals, S.L.	Litace	finasteride	5 mg	film-coated tablet	oral use
Spain	Accord Healthcare S.L.U.	Finasterida Normon	finasteride	1 mg	film-coated tablet	oral use
Spain	Alfasigma España, S.L.	Celganol	finasteride	1 mg	film-coated tablet	oral use
Spain	Almus Farmaceutica S.A.	Finasterida Almus	finasteride	5 mg	film-coated tablet	oral use
Spain	Almus Farmaceutica S.A.	Dutasterida/ Tamsulosina Almus Pharma	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Aristo Pharma Gmbh	Finasterida Aristo	finasteride	5 mg	film-coated tablet	oral use
Spain	Aristo Pharma Gmbh	Dutasterida/ Tamsulosina Aristo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Aristo Pharma Iberia, S.L.	Dutasterida Aristo	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Aurovitas Spain,s.A.U.	Finasterida Aurovitas	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Spain	Aurovitas Spain,s.A.U.	Finasterida Aurovitas	finasteride	1 mg	film-coated tablet	oral use
Spain	Aurovitas Spain,s.A.U.	Dutasterida Aurovitas	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Aurovitas Spain,s.A.U.	Dutasterida/ Tamsulosina Aurovitas	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Bluefish Pharmaceuticals Ab	Predser	finasteride	1 mg	film-coated tablet	oral use
Spain	Bluefish Pharmaceuticals Ab	Finasterida Bluefish	finasteride	5 mg	film-coated tablet	oral use
Spain	Chemo Ibérica, S.A.	Dutasterida Chemo Ibérica	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Exeltis Healthcare S.L	Dutamsin	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Farmalider, S.A.	Finasterida Benel Farmalider	finasteride	5 mg	film-coated tablet	oral use
Spain	Galenicum Derma S.L.	Dutacap	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Galenicum Health, S.L.	Dutasterida/ Tamsulosina Diagonalis	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Glaxosmithkline, S.A.	Avidart	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Glaxosmithkline, S.A.	Duodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Spain	GP-Pharm S.A.	Duplotrip	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Industria Química Y Farmacéutica Vir, S.A.	Finasterida Vir	finasteride	5 mg	film-coated tablet	oral use
Spain	Industria Química Y Farmacéutica Vir, S.A.	Dutasterida Vir	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Industrial Farmaceutica Cantabria, S.A.	Finasterida Ifc	finasteride	1 mg	film-coated tablet	oral use
Spain	Industrial Farmaceutica Cantabria, S.A.	Alocare	finasteride	1 mg	film-coated tablet	oral use
Spain	Kern Pharma, S.L.	Finasterida Kern Pharma	finasteride	5 mg	film-coated tablet	oral use
Spain	Kern Pharma, S.L.	Finasterida Kern Pharma	finasteride	1 mg	film-coated tablet	oral use
Spain	Kern Pharma, S.L.	Capikern	finasteride	1 mg	film-coated tablet	oral use
Spain	Kern Pharma, S.L.	Dutasterida Kern Pharma	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Kern Pharma, S.L.	Duprostat	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Krka, D.D., Novo Mesto	Dutasterida Krka	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Krka, D.D., Novo Mesto	Dutasterida/ Tamsulosina Krka	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Spain	Laboratoires Bailleul S.A.	Finasterida Biorga	finasteride	1 mg	film-coated tablet	oral use
Spain	Laboratorio Stada, S.L.	Finasterida Stada	finasteride	5 mg	film-coated tablet	oral use
Spain	Laboratorio Stada, S.L.	Finasterida Stada	finasteride	1 mg	film-coated tablet	oral use
Spain	Laboratorio Stada, S.L.	Dutasterida Stada	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Laboratorio Stada, S.L.	Dutasterida/ Tamsulosina Stadafarma	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Laboratorio Stada, S.L.	Dutasterida/ Tamsulosina Stada Stada	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Laboratorios Alter, S.A.	Finasterida/Tadalafilo Alter	finasteride, tadalafil	5 mg, 5 mg	film-coated tablet	oral use
Spain	Laboratorios Alter, S.A.	Finasterida Alter	finasteride	5 mg	film-coated tablet	oral use
Spain	Laboratorios Alter, S.A.	Biturol	finasteride, tadalafil	5 mg, 5 mg	film-coated tablet	oral use
Spain	Laboratorios Alter, S.A.	Neomyx	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Laboratorios Alter, S.A.	Dutasterida/ Tamsulosina Alter Genéricos	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Laboratorios Cinfa S.A.	Finasterida Cinfa	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Spain	Laboratorios Cinfa S.A.	Finasterida Cinfa	finasteride	1 mg	film-coated tablet	oral use
Spain	Laboratorios Cinfa S.A.	Dutasterida Cinfa	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Laboratorios Cinfa S.A.	Dutasterida/ Tamsulosina Cinfalab	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Laboratorios Cinfa S.A.	Dutasterida/ Tamsulosina Cinfa	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Laboratorios Combix, S.L.U.	Finasterida Combix	finasteride	1 mg	film-coated tablet	oral use
Spain	Laboratorios Combix, S.L.U.	Dutasterida Combix	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Laboratorios Combix, S.L.U.	Dutasterida/ Tamsulosina Combix Pharma	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Laboratorios Normon, S.A.	Finasterida Normon	finasteride	5 mg	film-coated tablet	oral use
Spain	Laboratorios Normon, S.A.	Finasterida Normon	finasteride	1 mg	film-coated tablet	oral use
Spain	Laboratorios Normon, S.A.	Dutasterida/ Tamsulosina Normogen	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Laboratorios Q Pharma S.L.	Dutaqur	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Laboratorios Q Pharma S.L.	Bidutam	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Spain	Laboratorios Salvat, S.A.	Ilmago	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Laboratorios Viñas, S.A.	Maxpil	finasteride	1 mg	film-coated tablet	oral use
Spain	Mabo-Farma, S.A	Finasterida Mabo	finasteride	5 mg	film-coated tablet	oral use
Spain	Mabo-Farma, S.A	Finasterida Mabo	finasteride	1 mg	film-coated tablet	oral use
Spain	Mabo-Farma, S.A	Dutasterida/ Tamsulosina Mabo	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Mana Pharma, S.L.	Dutasterida/ Tamsulosina Mana Pharma	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Neuraxpharm Spain, S.L.U.	Finasterida Qualigen	finasteride	5 mg	film-coated tablet	oral use
Spain	Neuraxpharm Spain, S.L.U.	Dutasterida/ Tamsulosina Qualigen	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Organon Salud, S.L.	Proscar	finasteride	5 mg	film-coated tablet	oral use
Spain	Organon Salud, S.L.	Propecia	finasteride	1 mg	film-coated tablet	oral use
Spain	Sandoz Farmacéutica, S.A.	Dutasterida/ Tamsulosina Sandoz	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Sandoz Farmacéutica, S.A.	Finasterida Sandoz	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Spain	Sandoz Farmacéutica, S.A.	Finasterida Sandoz	finasteride	1 mg	film-coated tablet	oral use
Spain	Tarbis Farma, S.L.	Finasterida Tarbis	finasteride	5 mg	film-coated tablet	oral use
Spain	Tarbis Farma, S.L.	Finasterida Tarbis	finasteride	1 mg	film-coated tablet	oral use
Spain	Tarbis Farma, S.L.	Dutasterida Tarbis	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Tarbis Farma, S.L.	Dutasterida/ Tamsulosina Tarbis	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Tecnimed España Ind. Fca., S.A.	Finasterida Tecnigen	finasteride	5 mg	film-coated tablet	oral use
Spain	Tecnimed España Ind. Fca., S.A.	Dutasterida Tecnigen	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Tecnimed España Ind. Fca., S.A.	Dutasterida/ Tamsulosina Tecnigen	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Teva B.V	Dutasterida/ Tamsulosina Teva	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Teva Pharma S.L.U.,	Finasteride Teva	finasteride	5 mg	film-coated tablet	oral use
Spain	Teva Pharma S.L.U.,	Finasteride Ratiopharm	finasteride	5 mg	film-coated tablet	oral use
Spain	Teva Pharma S.L.U.,	Finasterida Teva	finasteride	1 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Spain	Teva Pharma S.L.U.,	Finasterida Ratiopharm	finasteride	1 mg	film-coated tablet	oral use
Spain	Teva Pharma S.L.U.,	Dutasterida Teva	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Teva Pharma S.L.U.,	Dutasterida Ratiopharm	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Teva Pharma S.L.U.,	Dutasterida/ Tamsulosina Tevagen	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Teva Pharma S.L.U.,	Dutasterida/ Tamsulosina Ratio	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Towa Pharmaceutical S.A.	Finasterida Pensa	finasteride	5 mg	film-coated tablet	oral use
Spain	Towa Pharmaceutical S.A.	Dutasterida Pensa	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Towa Pharmaceutical S.A.	Dutasterida/ Tamsulosina Pensa	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Viatriis Limited	Finasterida Viatriis	finasteride	1 mg	film-coated tablet	oral use
Spain	Viatriis Limited	Dutasterida/ Tamsulosina Viatriis	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
Spain	Viatriis Pharmaceuticals, S.L.U.	Dutasterida Viatriis	dutasteride	0.5 mg	capsule, soft	oral use
Spain	Zentiva, K.S.	Dutasterida/ Tamsulosina Zentiva	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Sweden	2care4 Generics Aps	Prosterid	finasteride	1 mg	film-coated tablet	oral use
Sweden	Accord Healthcare B.V.	Finasteride Accord	finasteride	5 mg	film-coated tablet	oral use
Sweden	Accord Healthcare B.V.	Finasteride Accord	finasteride	1 mg	film-coated tablet	oral use
Sweden	Actavis Group Ptc Ehf.	Finasterid Actavis	finasteride	5 mg	film-coated tablet	oral use
Sweden	Amarox Pharma B.V.	Finasteride Amarox	finasteride	5 mg	film-coated tablet	oral use
Sweden	Aurobindo Pharma (Malta) Limited	Finasterid Aurobindo	finasteride	5 mg	film-coated tablet	oral use
Sweden	Glaxosmithkline (Ireland) Limited	Duagen	dutasteride	0.5 mg	capsule, soft	oral use
Sweden	Glaxosmithkline (Ireland) Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
Sweden	Krka, D.D., Novo Mesto	Finpros	finasteride	5 mg	film-coated tablet	oral use
Sweden	Laboratorios León Farma, S.A.	Dutasteride León Farma	dutasteride	0.5 mg	capsule, soft	oral use
Sweden	Medical Valley Invest Ab	Finasteride Medical Valley	finasteride	5 mg	film-coated tablet	oral use
Sweden	Medical Valley Invest Ab	Dutasteride Medical Valley	dutasteride	0.5 mg	capsule, soft	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Sweden	N.V. Organon	Propecia	finasteride	1 mg	film-coated tablet	oral use
Sweden	Sandoz A/S	Finasterid Sandoz	finasteride	5 mg	film-coated tablet	oral use
Sweden	Stada Arzneimittel Ag	Finasterid Stada	finasteride	5 mg	film-coated tablet	oral use
Sweden	Stada Arzneimittel Ag	Finasterid Stada	finasteride	1 mg	film-coated tablet	oral use
Sweden	Teva B.V	Finaset	finasteride	5 mg	film-coated tablet	oral use
Sweden	Teva Sweden Ab	Finasteride Teva	finasteride	5 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Accord Healthcare Limited	Finasteride Accord Healthcare	finasteride	5 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Accord Healthcare Limited	Finasteride Accord Healthcare	finasteride	1 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Accord Healthcare Limited	Dutasteride Accord Healthcare	dutasteride	0.5 mg	capsule, soft	oral use
United Kingdom (Northern Ireland)	Accord Healthcare Limited	Dutasteride/ Tamsulosin Hydrochloride Accord Healthcare	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Amarox Limited	Finasteride AmaroX	finasteride	5 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Amarox Limited	Finasteride AmaroX	finasteride	1 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Aristo Pharma GmbH	Dutasteride/ Tamsulosin Hydrochloride Aristo Pharma	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
United Kingdom (Northern Ireland)	Avianta Pharma Limited	Finasteride Avianta Pharma	finasteride	1 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited	Finasteride Bristol Laboratories	finasteride	5 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited	Finasteride Bristol Laboratories	finasteride	1 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Careforsons Limited	Finasteride Careforsons	finasteride	1 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Crescent Pharma Limited	Finasteride Crescent Pharma	finasteride	5 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited	Dutasteride Crescent Pharma	dutasteride	0.5 mg	capsule, soft	oral use
United Kingdom (Northern Ireland)	Dr. Reddy's Laboratories (UK) Ltd	Finasteride Dr. Reddy's Laboratories (Uk)	finasteride	5 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Dr. Reddy's Laboratories (UK) Ltd	Dutasteride/ Tamsulosin Hydrochloride Dr. Reddy's Laboratories (Uk)	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
United Kingdom (Northern Ireland)	Ennogen Healthcare Limited	Dutasteride Ennogen Healthcare	dutasteride	0.5 mg	capsule, soft	oral use
United Kingdom (Northern Ireland)	Ennogen Ip Limited	Dutasteride Ennogen Ip	dutasteride	0.5 mg	capsule, soft	oral use
United Kingdom (Northern Ireland)	Generics [UK] Limited	Finasteride Generics [uk]	finasteride	1 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Generics [UK] Limited	Finasteride Generics Uk	finasteride	5 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Generics [UK] Limited	Dutasteride/ Tamsulosin Hydrochloride Mylan	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
United Kingdom (Northern Ireland)	Glaxosmithkline UK Limited	Avodart	dutasteride	0.5 mg	capsule, soft	oral use
United Kingdom (Northern Ireland)	Glaxosmithkline UK Limited	Combodart	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
United Kingdom (Northern Ireland)	Glenmark Pharmaceuticals Europe Limited	Dutasteride/ Tamsulosin Hydrochloride Glenmark	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
United Kingdom (Northern Ireland)	Laboratorios León Farma, S.A.	Dutasteride/ Tamsulosin Hydrochloride Laboratorios León Farma	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
United Kingdom (Northern Ireland)	Milpharm Limited	Finasteride Milpharm	finasteride	5 mg	film-coated tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Milpharm Limited	Finasteride Milpharm	finasteride	1 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Milpharm Limited	Dutasteride Milpharm	dutasteride	0.5 mg	capsule, soft	oral use
United Kingdom (Northern Ireland)	Milpharm Limited	Dutasteride/ Tamsulosin Hydrochloride Milpharm	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
United Kingdom (Northern Ireland)	Northumbria Pharma Limited	Finasteride Northumbria Pharma	finasteride	1 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Organon Pharma (UK) Limited	Proscar	finasteride	5 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Organon Pharma (UK) Limited	Propecia	finasteride	1 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Rivopharm UK Ltd	Dutasteride Rivopharm Uk	dutasteride	0.5 mg	capsule, soft	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Rudipharm Limited	Finasteride North Star Healthcare	finasteride	5 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Rudipharm Limited	Finasteride	finasteride	1 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Sandoz Ltd	Finasteride Sandoz Ltd	finasteride	1 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Sandoz Ltd	Finasteride Sandoz	finasteride	5 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Strandhaven Limited T/A Somex Pharma	Finasteride Strandhaven Limited T/A Somex Pharma	finasteride	5 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Strandhaven Limited T/A Somex Pharma	Finasteride Strandhaven	finasteride	1 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Strides Pharma UK Limited	Dutasteride Strides Pharma UK	dutasteride	0.5 mg	capsule, soft	oral use

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Syri Limited T/A Thame Laboratories	Finasteride 1 Mg Film-Coated Tablets	finasteride	1 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Thornton & Ross Ltd	Dutasteride/ Tamsulosin Hydrochloride Stada	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use
United Kingdom (Northern Ireland)	Torrent Pharma (UK) Ltd.	Finasteride Torrent Pharma (Uk)	finasteride	5 mg	film-coated tablet	oral use
United Kingdom (Northern Ireland)	Zentiva Pharma UK Limited	Dutasteride Zentiva Pharma	dutasteride	0.5 mg	capsule, soft	oral use
United Kingdom (Northern Ireland)	Zentiva Pharma UK Limited	Dutrozen	dutasteride, tamsulosin hydrochloride	0.5 mg, 0.4 mg	capsule, hard	oral use

B. List of medicinal products and presentations recommended for maintenance

Member State EU/EEA	Marketing authorisation holder	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Belgium	Laboratoires Bailleul S.A.	Fynzur	finasteride	2.275 mg/ml	cutaneous spray, solution	cutaneous use
Bulgaria	Polichem S.A.	Финюве За Мъже	finasteride	2.275 mg/ml	cutaneous spray, solution	cutaneous use
Czech Republic	Polichem S.A.	Fynzur	finasteride	2.275 mg/ml	cutaneous spray, solution	cutaneous use
France	Laboratoires Bailleul S.A.	Fincrezo	finasteride	2.275 mg/ml	cutaneous spray, solution	cutaneous use
Germany	Laboratoires Bailleul S.A.	Fynzur Für Männer	finasteride	2.275 mg/ml	cutaneous spray, solution	cutaneous use
Germany	Polichem S.A.	Finjuve Für Männer	finasteride	2.275 mg/ml	cutaneous spray, solution	cutaneous use
Italy	Difa Cooper S.P.A.	Caretopic	finasteride	2.275 mg/ml	cutaneous spray, solution	cutaneous use
Luxembourg	Polichem S.A.	Finjuve Für Männer	finasteride	2.275 mg/ml	cutaneous spray, solution	cutaneous use
Portugal	Ifc Skincare Portugal	Finasterida Cantabria	finasteride	2.275 mg/ml	cutaneous spray, solution	cutaneous use
Romania	Polichem S.A.	Finjuve	finasteride	2.275 mg/ml	cutaneous spray, solution	cutaneous use
Spain	Industrial Farmaceutica Cantabria, S.A.	Alocare	finasteride	2.275 mg/ml	cutaneous spray, solution	cutaneous use