



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 April 2019  
EMA/241954/2019  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: finasteride

Procedure no.: PSUSA/00001392/201808

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<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
PROSCAR 5 mg, filmomhulde tabletten	not available	RVG 15482	MERCK SHARP & DOHME BV	NL
FINASTID 5 mg compresse rivestite con film	not available	028309019	NEOPHARMED GENTILI S.R.L.	IT
FINASTID 5 mg compresse rivestite con film	not available	028309021	NEOPHARMED GENTILI S.R.L.	IT
GENAPROST 5 mg compresse rivestite con film	not available	028371019	NEOPHARMED GENTILI S.R.L.	IT
GENAPROST 5 mg compresse rivestite con film	not available	028371021	NEOPHARMED GENTILI S.R.L.	IT
Propecia 1 mg filmdragerade tabletter	SE/H/0158/001	13713	MERCK SHARP & DOHME BV	FI
Propecia 1 mg, comprimé pelliculé	SE/H/0158/001	34009 349 065 4 1	MSD FRANCE	FR
Propecia 1 mg, comprimé pelliculé	SE/H/0158/001	34009 349 070 8 1	MSD FRANCE	FR
Propecia 1 mg, comprimé pelliculé	SE/H/0158/001	2009030231	MSD BELGIUM BVBA/SPRL	LU

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Propecia 1 mg compresse rivestite con film	SE/H/0158/001	034237014	MSD ITALIA S.R.L.	IT
Propecia 1 mg comprimidos revestidos por película	SE/H/0158/001	2832988	MERCK SHARP & DOHME, LDA.	PT
Propecia, filmovertrukne tabletter	SE/H/0158/001	30252	MERCK SHARP & DOHME BV	DK
Propecia 1 mg Filmtabletten	SE/H/0158/001	1-24532	MERCK SHARP & DOHME GES.M.B.H.	AT
Propecia 1 mg comprimidos recubiertos con película	SE/H/0158/001	62.441	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
Propecia 1 mg comprimidos revestidos por película	SE/H/0158/001	2832780	MERCK SHARP & DOHME, LDA.	PT
Propecia 1 mg compresse rivestite con film	SE/H/0158/001	034237038	MSD ITALIA S.R.L.	IT
Propecia 1 mg compresse rivestite con film	SE/H/0158/001	034237040	MSD ITALIA S.R.L.	IT
Propecia 1 mg compresse rivestite con film	SE/H/0158/001	034237053	MSD ITALIA S.R.L.	IT

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Propecia 1 mg Filmtabletten	SE/H/0158/001	44270.00.00	MSD SHARP & DOHME GMBH	DE
Propecia 1 mg filmdragerad tablett	SE/H/0158/001	13483	MERCK SHARP & DOHME BV	SE
Propecia 1 mg comprimidos revestidos por película	SE/H/0158/001	2832889	MERCK SHARP & DOHME, LDA.	PT
Propecia 1 mg comprimidos revestidos por película	SE/H/0158/001	2832582	MERCK SHARP & DOHME, LDA.	PT
Propecia 1 mg comprimidos revestidos por película	SE/H/0158/001	2832681	MERCK SHARP & DOHME, LDA.	PT
Propecia 1 mg tabletti, kalvopäällysteinen	SE/H/0158/001	13713	MERCK SHARP & DOHME BV	FI
Propecia 1 mg compresse rivestite con film	SE/H/0158/001	034237026	MSD ITALIA S.R.L.	IT
Propecia 1 mg, filmomhulde tabletten	SE/H/0158/001	RVG 27397	MERCK SHARP & DOHME BV	NL
Propecia 1 mg filmuháðaðar töflur	SE/H/0158/001	IS/1/02/010/01	MERCK SHARP & DOHME BV	IS

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Propecia 1 mg, comprimé pelliculé	SE/H/0158/001	34009 349 066 0 2	MSD FRANCE	FR
Propecia 1 mg, comprimé pelliculé	SE/H/0158/001	34009 349 068 3 1	MSD FRANCE	FR
Propecia 1 mg, comprimé pelliculé	SE/H/0158/001	34009 349 067 7 0	MSD FRANCE	FR
PROPECIA 1mg, επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/158/01/R02	52369/30-06-2016	VIANEX S.A.	GR
CHIBRO-PROSCAR 5 mg, comprimé pelliculé	not available	34009 335 248 4 5	MSD FRANCE	FR
CHIBRO-PROSCAR 5 mg, comprimé pelliculé	not available	34009 379 090 7 5	MSD FRANCE	FR
CHIBRO-PROSCAR 5 mg, comprimé pelliculé	not available	34009 379 091 3 6	MSD FRANCE	FR
CHIBRO-PROSCAR 5 mg, comprimé pelliculé	not available	34009 335 688 4 9	MSD FRANCE	FR
CHIBRO-PROSCAR 5 mg, comprimé pelliculé	not available	34009 335 249 0 6	MSD FRANCE	FR

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CHIBRO-PROSCAR 5 mg, comprimé pelliculé	not available	34009 335 690 9 9	MSD FRANCE	FR
CHIBRO-PROSCAR 5 mg, comprimé pelliculé	not available	34009 335 689 0 0	MSD FRANCE	FR
CHIBRO-PROSCAR 5 mg, comprimé pelliculé	not available	34009 335 691 5 0	MSD FRANCE	FR
PROSCAR 5 mg film-coated tablets	not available	PA 1286/17/1	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
Finasteride 5mg Film-coated Tablets	AT/H/0268/001	PL 04416/0816	SANDOZ LTD	UK
PROSCAR® 5 mg, Filmtabletten	not available	BE160124	MSD BELGIUM BVBA/SPRL	BE
PROSCAR® 5 mg, comprimés pelliculés	not available	BE160124	MSD BELGIUM BVBA/SPRL	BE
PROSCAR® 5 mg, filmomhulde tabletten	not available	BE160124	MSD BELGIUM BVBA/SPRL	BE
Proscar 5 mg filmdragerad tablett	not available	11644	MERCK SHARP & DOHME BV	SE

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PROSCAR 5 mg filmom obložene tablete	not available	HR-H-039526411	MERCK SHARP & DOHME D.O.O.	HR
Proscar 5 mg Filmtabletten	not available	1-19689	MERCK SHARP & DOHME GES.M.B.H.	AT
Propecia 1 mg compresse rivestite con film	SE/H/0158/001	034237014	MSD ITALIA S.R.L.	IT
Propecia 1 mg compresse rivestite con film	SE/H/0158/001	034237038	MSD ITALIA S.R.L.	IT
Propecia 1 mg compresse rivestite con film	SE/H/0158/001	034237040	MSD ITALIA S.R.L.	IT
Propecia 1 mg compresse rivestite con film	SE/H/0158/001	034237053	MSD ITALIA S.R.L.	IT
Propecia 1 mg compresse rivestite con film	SE/H/0158/001	034237026	MSD ITALIA S.R.L.	IT
Finasteride AHCL 1 mg compresse rivestite con film	NL/H/1149/001	039595020	ACCORD HEALTHCARE LIMITED	IT
Finasteride AHCL 1 mg compresse rivestite con film	NL/H/1149/001	039595184	ACCORD HEALTHCARE LIMITED	IT

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Finasteride AHCL 1 mg compresse rivestite con film	NL/H/1149/001	039595196	ACCORD HEALTHCARE LIMITED	IT
Finasteride AHCL 1 mg compresse rivestite con film	NL/H/1149/001	039595018	ACCORD HEALTHCARE LIMITED	IT
Finasteride Accord 1 mg apvalkotas tabletės	NL/H/1149/001	09-0154	ACCORD HEALTHCARE LIMITED	LV
PROSCAR® 5 mg Filmtabletten Wirkstoff: Finasterid Zur Anwendung bei männlichen Patienten	not available	42859.00.00	MSD SHARP & DOHME GMBH	DE
Proscar 5 mg tabletter	not available	7841	MERCK SHARP & DOHME BV	NO
PROSCAR, 5 mg, tabletki powlekane	not available	R/3621	MSD POLSKA SP. Z O.O.	PL
PROSCAR 5 mg comprimate filmate	not available	5885/2013/01	MERCK SHARP & DOHME ROMANIA SRL	RO
PROSCAR 5 mg comprimate filmate	not available	5885/2013/02	MERCK SHARP & DOHME ROMANIA SRL	RO



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PROSCAR® 5 mg, comprimés pelliculés	not available	2003107721	MSD BELGIUM BVBA/SPRL	LU
Prostide 5 mg filmsko obložene tablete	not available	H/97/01301/001	MERCK SHARP & DOHME INOVATIVNA ZDRAVILA D.O.O.	SI
PROSCAR 5 mg comprimidos recubiertos con película	not available	59.830	LABORATORIOS CHIBRET, S.A.	ES
Propecia 1 mg filmsko obložene tablete	not available	H/99/01294/001	MERCK SHARP & DOHME INOVATIVNA ZDRAVILA D.O.O.	SI
PROPECIA 1 mg, tabletki powlekane	not available	4602	MSD POLSKA SP. Z O.O.	PL
Propecia 1 mg comprimate filmate	not available	9711/2017/01	MERCK SHARP & DOHME ROMANIA SRL	RO
PROPECIA 1 mg Film-Coated Tablets	not available	MA058/00801	MERCK SHARP & DOHME LTD.	MT
Proscar 5 mg comprimidos revestidos por película	not available	2133189	MERCK SHARP & DOHME, LDA.	PT
Proscar 5 mg comprimidos revestidos por película	not available	2133288	MERCK SHARP & DOHME, LDA.	PT

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Proscar 5 mg comprimidos revestidos por película	not available	2133387	MERCK SHARP & DOHME, LDA.	PT
PROSCAR επικαλυμμένο με λεπτό υμένιο δισκίο 5mg/TAB	not available	21729/14-11-2014	VIANEX S.A.	GR
PROSCAR® 5mg film-coated Tablets (finasteride)	not available	PL 0025/0279	MERCK SHARP & DOHME LTD.	UK
Finasteride 5 mg film-coated tablets	not available	PL 21880/0052	MEDREICH PLC	UK
Finasteride Teva Generics 1 mg compresse rivestite con film	PT/H/2278/001	040952057	TEVA ITALIA S.R.L.	IT
Finasteride Teva Generics 1 mg compresse rivestite con film	PT/H/2278/001	040952020	TEVA ITALIA S.R.L.	IT
Finasteride Teva Generics 1 mg compresse rivestite con film	PT/H/2278/001	040952071	TEVA ITALIA S.R.L.	IT
Finasteride Teva Generics 1 mg compresse rivestite con film	PT/H/2278/001	040952032	TEVA ITALIA S.R.L.	IT
Finasteride Teva Generics 1 mg compresse rivestite con film	PT/H/2278/001	040952044	TEVA ITALIA S.R.L.	IT

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Finasteride 1 mg Film-coated Tablets	PT/H/2278/001	PL 00289/0826	TEVA UK LIMITED	UK
Finasteride Teva Generics 1 mg compresse rivestite con film	PT/H/2278/001	040952069	TEVA ITALIA S.R.L.	IT
PROSCAR 5 mg compresse rivestite con film	not available	028308017	MERCK SHARP & DOHME LTD.	IT
PROSCAR 5 mg compresse rivestite con film	not available	028308029	MERCK SHARP & DOHME LTD.	IT
PROSTIDE 5 mg compresse rivestite con film	not available	028356018	ALFASIGMA S.P.A.	IT
PROSTIDE 5 mg compresse rivestite con film	not available	028356020	ALFASIGMA S.P.A.	IT
Propecia® 1 mg Film-Coated Tablets	not available	PL 0025/0351	MERCK SHARP & DOHME LTD.	UK
PROPECIA 1 mg, film-coated tablets	not available	18318	MERCK SHARP & DOHME BV	CY
Proscar 5 mg filmdragerade tabletter	not available	10751	MERCK SHARP & DOHME BV	FI

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PROSCAR 5 mg tabletti, kalvopäällysteinen	not available	10751	MERCK SHARP & DOHME BV	FI
Finasteride 5 mg Film-coated tablets	not available	PL 40378/0124	APTIL PHARMA LIMITED	UK
Pilus 1mg compressa rivestita con film	not available	034824019	NEOPHARMED GENTILI SPA	IT
Pilus 1mg compressa rivestita con film	not available	034824033	NEOPHARMED GENTILI SPA	IT
Pilus 1mg compressa rivestita con film	not available	034824045	NEOPHARMED GENTILI SPA	IT
Pilus 1mg compressa rivestita con film	not available	034824058	NEOPHARMED GENTILI SPA	IT
PILUS 1mg compressa rivestita con film	not available	034824021	NEOPHARMED GENTILI SPA	IT