



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2018
EMA/381051/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: finasteride

Procedure no.: PSUSA/00001392/201708



| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|--|------------------------------|-------------------------------|------------------------------------|--|
| Proscar 5 mg Filmtabletten | not available | 1-19689 | MERCK SHARP & DOHME GES.M.B.H. | AT |
| Propecia 1 mg Filmtabletten | SE/H/0158/001 | 1-24532 | MERCK SHARP & DOHME GES.M.B.H. | AT |
| 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 |
| PROPECIA 1 mg, film-coated tablets | not available | 18318 | MERCK SHARP & DOHME BV | CY |
| PROPECIA® potahované tablety | not available | 87/244/99-C | MERCK SHARP & DOHME BV | CZ |
| PROSCAR® 5 mg Filmtabletten Wirkstoff: Finasterid Zur Anwendung bei männlichen Patienten | not available | 42859.00.00 | MSD SHARP & DOHME GMBH | DE |
| PROPECIA® 1 mg Filmtabletten | SE/H/0158/001 | 44270.00.00 | MSD SHARP & DOHME GMBH | DE |
| Propecia, fillovertrukne tabletter | SE/H/0158/001 | 30252 | MERCK SHARP & DOHME BV | DK |
| PROSCAR 5 mg comprimidos recubiertos con película | not available | 59.830 | LABORATORIOS CHIBRET, S.A. | ES |
| Propecia 1 mg comprimidos recubiertos con película | SE/H/0158/001 | 62.441 | MERCK SHARP & DOHME DE ESPAÑA, S.A | ES |
| Proscar 5 mg filmdragerade tabletter | not available | 10751 | MERCK SHARP & DOHME BV | FI |
| PROSCAR 5 mg tabletti, kalvopäällysteinen | not available | 10751 | MERCK SHARP & DOHME BV | FI |
| Propecia 1 mg filmdragerade tabletter | SE/H/0158/001 | 13713 | MERCK SHARP & DOHME BV | FI |
| Propecia 1 mg tabletti, kalvopäällysteinen | SE/H/0158/001 | 13713 | MERCK SHARP & DOHME BV | FI |

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| 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 |
| 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 |
| 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 | 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 |
| PROSCAR επικαλυμμένο με λεπτό υμένιο δισκίο 5mg/TAB | not available | 21729/14-11-2014 | VIANEX S.A. | GR |
| PROSCAR® 5 mg filmom obložene tablete | not available | HR-H-039526411 | MERCK SHARP & DOHME D.O.O. | HR |
| PROSCAR 5 mg film-coated tablets | not available | PA 1286/17/1 | MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD | IE |

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| Propecia 1 mg filmuhúðaðar töflur | SE/H/0158/001 | IS/1/02/010/01 | MERCK SHARP & DOHME BV | IS |
| 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 |
| 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 |
| 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 |
| Pilus 1mg compressa rivestita con film | not available | 034824019 | NEOPHARMED GENTILI S.R.L. | IT |
| Pilus 1mg compressa rivestita con film | not available | 034824033 | NEOPHARMED GENTILI S.R.L. | IT |
| Pilus 1mg compressa rivestita con film | not available | 034824045 | NEOPHARMED GENTILI S.R.L. | IT |
| Pilus 1mg compressa rivestita con film | not available | 034824058 | NEOPHARMED GENTILI S.R.L. | IT |
| PILUS 1mg compressa rivestita con film | not available | 034824021 | NEOPHARMED GENTILI 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 |
| 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 |
| 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 Teva Generics 1 mg compresse rivestite con film | UK/H/4251/001 | 040952057 | TEVA ITALIA S.R.L. | IT |
| Finasteride Teva Generics 1 mg compresse rivestite con film | UK/H/4251/001 | 040952020 | TEVA ITALIA S.R.L. | IT |

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| Finasteride Teva Generics 1 mg compresse rivestite con film | UK/H/4251/001 | 040952071 | TEVA ITALIA S.R.L. | IT |
| Finasteride Teva Generics 1 mg compresse rivestite con film | UK/H/4251/001 | 040952032 | TEVA ITALIA S.R.L. | IT |
| Finasteride Teva Generics 1 mg compresse rivestite con film | UK/H/4251/001 | 040952044 | TEVA ITALIA S.R.L. | IT |
| Finasteride Teva Generics 1 mg compresse rivestite con film | UK/H/4251/001 | 040952069 | TEVA ITALIA S.R.L. | IT |
| 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 |
| PROSCAR® 5 mg, comprimés pelliculés | not available | 2003107721 | MSD BELGIUM BVBA/SPRL | LU |
| Propecia 1 mg, comprimé pelliculé | SE/H/0158/001 | 2009030231 | MSD BELGIUM BVBA/SPRL | LU |
| Finasteride Accord 1 mg apvalkotās tabletes | NL/H/1149/001 | 09-0154 | ACCORD HEALTHCARE LIMITED | LV |
| Finasteride Accord 1 mg apvalkotās tabletes | NL/H/1149/001 | 09-0154 | ACCORD HEALTHCARE LIMITED | LV |

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| PROSCAR® 5mg film-coated Tablets (finasteride) | not available | MA 058/00701 | MERCK SHARP & DOHME LTD. | MT |
| PROPECIA 1 mg Film-Coated Tablets | not available | MA058/00801 | MERCK SHARP & DOHME LTD. | MT |
| PROSCAR 5 mg, filmomhulde tabletten | not available | RVG 15482 | MERCK SHARP & DOHME BV | NL |
| Propecia 1 mg, filmomhulde tabletten | SE/H/0158/001 | RVG 27397 | MERCK SHARP & DOHME BV | NL |
| Proscar 5 mg tableter | not available | 7841 | MERCK SHARP & DOHME BV | NO |
| PROPECIA 1 mg, tabletki powlekane | not available | 4602 | MSD POLSKA SP. Z O.O. | PL |
| PROSCAR, 5 mg, tabletki powlekane | not available | R/3621 | MSD POLSKA SP. Z O.O. | PL |
| 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 |
| Proscar 5 mg comprimidos revestidos por película | not available | 2133387 | MERCK SHARP & DOHME, LDA. | PT |
| Propecia 1 mg comprimidos revestidos por película | SE/H/0158/001 | 2832988 | MERCK SHARP & DOHME, LDA. | PT |
| Propecia 1 mg comprimidos revestidos por película | SE/H/0158/001 | 2832780 | MERCK SHARP & DOHME, LDA. | PT |
| 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 |

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| Propecia 1 mg comprimidos revestidos por película | SE/H/0158/001 | 2832681 | MERCK SHARP & DOHME, LDA. | PT |
| Propecia 1 mg comprimate filmate | not available | 9711/2017/01 | MERCK SHARP & DOHME ROMANIA SRL | RO |
| 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 |
| PROPECIA 1 mg filmdragerad tablett | SE/H/0158/001 | 13483 | MERCK SHARP & DOHME BV | SE |
| Proscar 5 mg filmdragerad tablett | not available | 11644 | MERCK SHARP & DOHME BV | SE |
| Prostide 5 mg filmsko obložene tablete | not available | H/97/01301/001 | MERCK SHARP & DOHME INOVATIVNA ZDRAVILA D.O.O. | SI |
| Propecia 1 mg filmsko obložene tablete | not available | H/99/01294/001 | MERCK SHARP & DOHME INOVATIVNA ZDRAVILA D.O.O. | SI |
| Finasteride 5 mg film-coated tablets | not available | PL 21880/0052 | MEDREICH PLC | UK |
| Finasteride 5mg Tablets | AT/H/0268/001 | PL 04416/0816 | SANDOZ LTD | UK |
| PROSCAR® 5mg film-coated Tablets (finasteride) | not available | PL 0025/0279 | MERCK SHARP & DOHME LTD. | UK |
| Propecia® 1 mg Film-Coated Tablets | not available | PL 0025/0351 | MERCK SHARP & DOHME LTD. | UK |
| Finasteride 1 mg Film-coated Tablets | UK/H/4251/001 | PL 00289/0826 | TEVA UK LIMITED | UK |