



July 5, 2018

Important drug information

Potential risks associated with the use of finasteride-containing medications (1 mg and 5 mg dosages), and recommendations to educate your patients.

Dear Doctor:

The companies listed below, in cooperation with the Federal Institute for Drugs and Medical Devices (BfArM), issue this safety information about finasteride-containing drugs when prescribed for “androgenetic alopecia” and “benign prostatic hyperplasia.”

Synopsis

During and after the intake of finasteride, **side effects such as sexual dysfunction, as well as mental impairment symptoms or disorders**, have been reported since its market introduction. In order to support you in counseling your patients on the risk-benefit considerations before making a decision to begin therapy, especially when treating androgenetic alopecia (1 mg dosage), we would like to draw your attention to the following safety issues:

- Patients should be aware of the risk of sexual dysfunction (including erectile dysfunction, ejaculation disorder, and decreased libido) when starting finasteride therapy. Patients should also be informed that, based on individual patient case reports, sexual dysfunction may persist for more than 10 years after discontinuation of the therapy.

- Patients should also be advised that mood changes (including depressive mood, depression and suicidal thoughts) have been reported in patients treated with finasteride.
- Last year, the product information and leaflet for the 1 mg dose of finasteride products changed an adverse reaction from “depressive mood” to “depression.” In addition, a warning label has been added to the product instructions leaflet of all finasteride-containing medications. Patients treated with finasteride should be monitored for psychiatric symptoms. If a patient develops psychiatric symptoms using 1 mg finasteride, treatment should be stopped, and the patient should be advised to seek medical attention. If a patient develops psychiatric symptoms using 5 mg finasteride, the patient should be advised to seek medical attention.
- On the recommendation of the European Medicines Agency, “anxiety” is included as a new side effect in the specialized finasteride product information.
- Further details can be found in the respective specialized information.

Background of safety concerns

Finasteride is an active substance in the group of 5-alpha-reductase inhibitors, which has been approved for the treatment of androgenetic alopecia in Germany since 1998 in the 1 mg dosage, and approved in the 5 mg dosage for benign prostatic hyperplasia (BPH) since 1994. Finasteride-containing medicaments, like any other drugs, are subject to permanent control by pharmaceutical companies and the regulatory authorities. This of course includes the side effects and risk profile. As a result of this ongoing monitoring, you have received this Red Hand Letter today to minimize potential patient risks.

Requesting notification of side effects

Health care professionals are required to report any suspected case of adverse reactions to the corresponding authorization holder.

Suspected cases of side effects can also be reported to the Federal Institute for Drugs and Medical Devices (BfArM): electronically via the Internet (www.bfarm.de - Pharmaceuticals - Pharmacovigilance - Risks); in writing to the postal address Kurt-Georg-Kiesinger Allee 3, 53175 Bonn; or by fax to 0228/2075207.

This Red Hand Letter covers all finasteride-containing medications and has been prepared by the companies listed below:

Authorization holders and distributors of finasteride-containing medication products in Germany:

1 A Pharma GmbH, Keltenring 1 + 3, 82041 Oberhaching, www.lapharma.de
(Finasterid - 1 A Pharma 1 mg Filmtabletten, Finasterid - 1 A Pharma 5 mg Filmtabletten)

AbZ-Pharma GmbH, Graf-Arco-Str. 3, 89079 Ulm, www.abz.de
(Finasterid AbZ 1 mg Filmtabletten, Finasterid AbZ 5 mg Filmtabletten, Finasterid-CT 1 mg Filmtabletten Finasterid-CT 5 mg Filmtabletten)

acis Arzneimittel GmbH, lil-Dagover-Ring 7, 82031 Grünwald, www.acis.del
(Finasterid acis 1 mg Filmtabletten)

ALIUD GmbH, Gottlieb-Daimler-Str. 19, 89150 Laichingen, www.aliud.de
(Finasterid AL 1 mg Filmtabletten, Finasterid AL 5mg Filmtabletten)

APOGEPHA Arzneimittel GmbH, Kyffhäuserstr. 27, 01309 Dresden, www.apogepha.de (Proscin 5 mg Filmtabletten)

Aristo Pharma GmbH, Wallenroder Str. 8-10, 13435 Berlin, www.aristo-pharma.de
(Finasterid Aristo 5 mg Filmtabletten, Finaristo 1 mg Filmtabletten)

Aurobindo Pharma GmbH, Willy-Brandt-Allee 2, 81829 München, www.aurobindo-pharma.de (Finasterid Aurobindo 1 mg Filmtabletten, Finasterid Aurobindo 5 mg Filmtabletten)

axcount Generika GmbH, Max-Planck-Str. 36 d, 61381 Friedrichsdorf, www.axcount.de (Finasterid axcount 1 mg Filmtabletten Finasterid axcount 5 mg Filmtabletten)

axicorp Pharma GmbH, Max-Planck-Str. 36b, 61381 Friedrichsdorf, www.axicorp.del (Proscar 5 mg Filmtablette)

BB Farma S.r.l., Viale Europa 160, 21017 Samarate (VA), Italien; www.bbfarma.com (Finasterid STADA 5 mg Filmtabletten)

biome pharma GmbH, Josef-Dietzgen-Straße 3, 53773 Hennef, www.biomopharma.de (finasterid-biomo 5 mg Filmtabletten)

BERAGENA Arzneimittel GmbH, Rheinstr. 93-95, 76532 Baden-Baden, www.beragena.de (Proscar 5 mg Filmtabletten)

Bluefish Pharmaceuticals AB, Gävlegatan 22, 11330 Stockholm, Schweden, www.bluefishpharma.com. Mitvertrieb: Bluefish Pharma GmbH, Im Leuschnerpark 4, 64347 Griesheim (Finasterid Bluefish 5 mg Filmtabletten). Dermapharm AG, lil-Dagover-Ring 7, 82031 Grünwald, www.dermapharm.del (Finapill mg Filmtabletten)

Dr. R. Pflieger Chemische Fabrik GmbH, Dr.-Robert-Pflieger-Str. 12, 96052 Bamberg, www.dr.pflieger.de (Finural5 mg, Finural5 mg Filmtabletten)

EurimPharm Arzneimittel GmbH, EurimPark 8, 83416 Saaldorf-Surheim,
www.eurim.de (Proscar 5mg Filmtabletten)

Heumann Pharma GmbH & Co. Generica KG, Südwestpark 50, 90449 Nürnberg,
www.heumann.de (Finasterid Heumann 1 mg Filmtabletten, Finasterid Heumann 5 mg Filmtabletten)

Hexal AG, Industriestr. 25, 83607 Holzkirchen, www.hexal.de
(Finasterid Sandoz 5 mg Filmtabletten, Finasterid HEXAL 5 mg Filmtabletten, FinaHAIR 1 mg Filmtabletten)

Hormosan Pharma GmbH, Hanauer Landstraße 139-143, 60314 Frankfurt am Main, www.hormosan.de/ (Finasterid-Hormosan 1 mg Filmtabletten, Finasterid-Hormosan 5 mg Filmtabletten)

Medicopharm AG, Stangenreiterstr. 4, 873131 Nußdorf am Inn,
www.medicopharm.de (Finasterid 5 mg Medicopharm Filmtabletten)

mibe GmbH Arzneimittel, Münchener Str. 15, 06796 Brehna, www.mibe.de/
(Finamed 5 mg Filmtabletten)

MSD Sharp & Dohme GmbH - Lindenplatz 1, 85540 Haar, www.msd.de (Propecia 1 mg Filmtabletten, Proscar 5 mg Filmtabletten)

Orifarm GmbH, Fixheider Str. 4, 51381 Leverkusen, www.orifarm.de (Proscar 5 mg Filmtabletten)

Pharma Gerke Arzneimittelvertriebs GmbH, Friedrich-Bergius-Str. 13, 0-41516 Grevenbroich, www.pharma-gerke.de (Proscar 5 mg Filmtabletten)

PUREN Pharma GmbH & Co. KG, Willy-Brandt-Allee 2, 81829 München,
www.puren-pharma.de (FinaPUREN 1 mg Filmtabletten, Finasterid PUREN 1 mg Filmtabletten, Finasterid PUREN 5 mg Film tabletten)

ratiopharm GmbH, Graf-Arco-Str. 3, 89079 Ulm, www.ratiopharm.de (Finasterid-ratiopharm 1 mg Filmtabletten, Finasterid-ratiopharm 5 mg Filmtabletten)

STAOAPHARM GmbH, Stadastraße 2 -18, 61118 Bad Viibel, www.stadapharm.de/
(Finasterid STADA ®1 mg Filmtabletten, Finasterid STADA ®5mg Filmtabletten)

TAO Pharma GmbH, Heinz-Lohmann-Str. 5, 27472 Cuxhaven, www.tad.de/
(Finascar 5 mg Filmtabletten)

TECNIMEOE - Sociedade Tecnico-Medicinal, S.A., Rua da Tapada Grande, no.2, 2710-089 Abrunheira, Sintra, Portugal, www.tecnimede.com
(Finasterid Tecnimede 5 mg Filmtabletten)

Uropharm AG, Erfurtstraße 64, 53125 Bonn, www.uropharm.de (Finasterid-Uropharm 5 mg, Filmtabletten)

Winthrop Arzneimittel GmbH/Zentiva Pharma GmbH, Brüningstr 50, 65926 Frankfurt am Main, www.zentiva.de/(Finasterid Winthrop 5mg Filmtabletten)