

Editor's note: This English translation was done by a third party. The original news report can be accessed [here](#).

ANSM News

Feb. 1, 2019 (updated Dec. 1, 2021)

Finasteride: Reminder regarding the risks of psychiatric disorders and sexual function

ANSM wishes to alert patients and health care professionals to the risks of psychiatric disorders and sexual function during treatment with finasteride, as well as what to do in the event of the occurrence of these adverse effects.

A letter [below] is being sent to all health care professionals likely to prescribe, dispense or monitor patients treated with finasteride.

In order to promote discussion between patients and their doctors, in particular on the benefits and risks of finasteride, an information document will be made available at a later stage.

Finasteride at a dose of 1 mg (Propecia and generics) is indicated for the treatment of hair loss (androgenetic alopecia), in men only. At a dose of 5 mg (Chibro-Proscar and generics), it is indicated for the treatment of symptoms of benign prostatic hyperplasia.

In October 2017, following changes to the information documents (SPC and package leaflet) for finasteride 1 mg and finasteride 5 mg, ANSM issued information to warn of the risks of mood changes, suicide and depression, and to advise ceasing treatment in the event of any psychiatric symptoms.

INFORMATION TRANSMITTED UNDER THE AUTHORITY OF ANSM

Letter to Health Professionals

February 2019

Finasteride (Propecia, Chibro-Proscar, generics): reminder of the risks of sexual disorders and psychiatric disorders

Information for general practitioners, dermatologists, psychiatrists, endocrinologists, andrologists, urologists, neurologists, geriatricians and community pharmacists.

Madam, Sir, Dear Sister, Dear Brother:

In agreement with the National Agency for the Safety of Medicines and Health Products (ANSM), laboratories Marketing Authorization Holders of finasteride-based specialties would like to remind you of some safety information about medicines containing finasteride to treat “androgenetic alopecia” at a dose of 1mg, and “benign prostatic hypertrophy” at a dose of 5mg.

Summary

- Finasteride-based medicinal products are indicated in humans only. They are strictly contraindicated in women.
- Adverse effects, such as psychiatric disorders, as well as sexual-function disorders, have been reported during and after the use of finasteride.

- Patients should be informed of the risk of these disorders:

—PSYCHIATRIC DISORDERS: Anxiety, mood changes, including depressive mood, depression and, less frequently, suicidal thoughts. The appearance of such symptoms should be closely monitored.

—SEXUAL DISORDERS: Sexual dysfunction (including erectile dysfunction, ejaculation and decreased libido). Disorders of sexual function in some patients may persist after stopping treatment.

- If a patient on finasteride 1mg (Propecia and generics, prescribed for alopecia) develops psychiatric symptoms, he should stop his treatment and consult a doctor.
- If a patient on finasteride 5mg (Chibro-Proscar and generics, prescribed for benign hypertrophy of the prostate) develops psychiatric symptoms, the patient cannot stop his treatment alone but must promptly consult a doctor.
- In the case of patients being treated for androgenic alopecia (finasteride 1mg), it is appropriate to discuss with the patient the relationship between the expected benefits and the risks incurred.

Further information

Finasteride, a 5-alpha reductase inhibitor, has been marketed in France at a dose of 1mg for the treatment of androgenetic alopecia since 1999 and at a dose of 5mg for the treatment of benign prostatic hypertrophy (HBP) since 1992.

Declaration of adverse effects

Immediately report any adverse reactions suspected to be due to a medicine to your doctor. Regional Pharmacovigilance Center or at www.signalement-sante.gouv.fr.

For more information on medicines, see ansm.sante.fr or base-donneepublic.medicaments.gouv.fr

Medical information

If you have any questions or need additional information, please contact the respective manufacturers:

| Product | Licensed Corporation |
|---|--|
| PROPECIA® (finastéride 1 mg) CHIBRO-PROSCAR® (finastéride 5 mg) | MSD France. Tél. 01 80 46 40 40 ou information.medicale@msd.com ou http://www.msd-france.com |
| CHIBRO-PROSCAR®, comprimé pelliculé (finastéride 5 mg) | Mediwin Limited. (Importateur Parallèle) Tél. +44 3306 841 100 |
| FINASTERIDE ALTER 5 mg, comprimé pelliculé | Laboratoires ALTER Tél : 01 69 29 83 00 |
| FINASTERIDE ARROW GENERIQUES 1 mg, comprimé pelliculé FINASTERIDE ARROW LAB 5 mg, comprimé pelliculé | Laboratoire Arrow Information médicale et Pharmacovigilance : 04 72 71 63 97 |
| FINASTERIDE ALMUS 5 mg, comprimé pelliculé | ALMUS Information médicale et pharmacovigilance : Tél : 01 40 80 18 44: |
| FINASTERIDE BAILLEUL 1 mg, comprimé pelliculé | Laboratoires BAILLEUL Information médicale et Pharmacovigilance – Tél : 01 56 33 11 11 |
| Finhair® Gé (finastéride 1mg), comprimé pelliculé | Laboratoires Expanscience Information médicale et pharmacovigilance : 01.43.34.75.15 pharmacovigilance@expanscience.com |
| FINASTERIDE SANDOZ 1 mg, comprimé pelliculé FINASTERIDE SANDOZ 5 mg, comprimé pelliculé | Titulaire/Exploitant SANDOZ SAS Information médicale et Pharmacovigilance Tel : 0800 455 799 |
| FINASTERIDE ACCORD 5 mg, comprimé pelliculé | Accord Healthcare France Information médicale et Pharmacovigilance : Tel : 03.20.40.17.70 (touche 2) @ : infofrance@accord-healthcare.com |
| FINASTERIDE MYLAN 1 mg, comprimé pelliculé FINASTERIDE MYLAN 5 mg, comprimé pelliculé | MYLAN SAS Information médicale et Pharmacovigilance Tel : 0800 123 550 (Service & appel gratuits) |
| FINASTERIDE CRISTERS 1 mg, comprimé pelliculé FINASTERIDE CRISTERS 5 mg, comprimé pelliculé | Laboratoire CRISTERS Information médicale et pharmacovigilance Tel : 01 42 04 94 20 Fax : 01 42 04 94 21 pharmacovigilance@cristers.com |
| FINASTERIDE ZENTIVA 5 mg, comprimé pelliculé | Laboratoires Zentiva France Information médicale : 0 800 089 219 |
| FINASTERIDE EG 1 mg, comprimé pelliculé FINASTERIDE EG 5 mg, comprimé pelliculé | EG LABO - Laboratoires Eurogenerics Information médicale et Pharmacovigilance : 01 46 94 86 86 pharmacovigilance@eglabo.fr |
| FINASTERIDE TEVA 1 mg, comprimé pelliculé FINASTERIDE TEVA 5 mg, comprimé pelliculé | TEVA Santé, Information médicale et Pharmacovigilance Tél : 0800 513 411 |
| FINASTERIDE RANBAXY 5 mg, comprimé pelliculé | RANBAXY Pharmacie Génériques Information médicale et Pharmacovigilance Tél : 01 41 44 44 50 Fax : 01 41 44 44 90 |
| Finastéride Zydus 1 mg, comprimé pelliculé Finastéride Zydus 5 mg, comprimé pelliculé | Zydus France Tél. : 01 41 19 18 50 – email : contact@zydusfrance.com |
| FINASTERIDE BIOGARAN 5 mg comprimé pelliculé FINASTERIDE BIOGARAN 1 mg comprimé pelliculé | Laboratoire Biogaran Information médicale et Pharmacovigilance Tél : 0800 970 109 www.biogaran.fr |