

*Editor's note: This English translation was done by a third party. The original letter can be accessed at the [ANSM website](#).*

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### **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](http://www.signalement-sante.gouv.fr).

For more information on medicines, see [ansm.sante.fr](http://ansm.sante.fr) or [base-donnepublic.medicaments.gouv.fr](http://base-donnepublic.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 <a href="mailto:information.medicale@msd.com">information.medicale@msd.com</a> ou <a href="http://www.msd-france.com">http://www.msd-france.com</a>
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 <a href="mailto:pharmacovigilance@expanscience.com">pharmacovigilance@expanscience.com</a>
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) @ : <a href="mailto:infofrance@accord-healthcare.com">infofrance@accord-healthcare.com</a>
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 <a href="mailto:pharmacovigilance@cristers.com">pharmacovigilance@cristers.com</a>
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 <a href="mailto:pharmacovigilance@eglabo.fr">pharmacovigilance@eglabo.fr</a>
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 Tel : 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 : <a href="mailto:contact@zydusfrance.com">contact@zydusfrance.com</a>
FINASTERIDE BIOGARAN 5 mg comprimé pelliculé FINASTERIDE BIOGARAN 1 mg comprimé pelliculé	Laboratoire Biogaran Information médicale et Pharmacovigilance Tél : 0800 970 109 <a href="http://www.biogaran.fr">www.biogaran.fr</a>