ANSM News May 24, 2023

Finasteride 1 mg (Propecia and generics): addition of warning notices on boxes to reinforce information on adverse effects

Editor's note: This English translation was done by a third party. The original digital content can be accessed <u>here</u>.

Update of May 24, 2023

Beginning April 28, 2023, finasteride 1 mg boxes have been gradually marketed with a red box on their main (front) side, indicating that sexual and/or psychiatric adverse effects may occur during and after treatment, accompanied by a QR code that links to our <u>Finasteride 1 mg and Hair Loss</u> (English) dossier.

Additionally, the Organon laboratory informed ANSM that it has discontinued the marketing of Propecia 1 mg (84 tablets) effective January 31, 2023, as well as of Propecia 1 mg (28 tablets) effective April 27, 2023. If necessary, pharmacists will dispense one of their generics.

Consult the list of medicines containing finasteride marketed in France.

As an extension of our actions aimed at strengthening patient information on the potential adverse reactions, in particular psychiatric and sexual, of medicinal products containing finasteride 1 mg, and on case reports of those reactions, we have asked the respective manufacturers to affix a warning message, accompanied by a QR code, to the boxes of those medicines.

Thus, on April 28, 2023 at the latest, all boxes of medicines containing finasteride 1 mg will include on their main (front) face:

- A red box indicating that sexual and/or psychiatric adverse effects may occur during and after treatment;
- A QR code referring to our Finasteride 1 mg and hair loss dossier.

At the same time, the information sheet intended to make patients aware of these risks of psychiatric and/or sexual effects has been updated.

Download the patient information sheet (30/11/2022) (English)

We remind you that finasteride 1 mg is prescribed for mild forms of alopecia (baldness) of androgenetic origin in men ages 18 to 41 years.

Information for patients

Finasteride can cause adverse effects, in particular psychiatric and sexual effects, the impact of which can be significant. It is essential to know them before starting a treatment and to be followed throughout this treatment.

If you experience any side effects after taking finasteride, you can report it yourself if a healthcare professional has not already done so. To help you with this declaration, you can <u>consult the video</u> devoted specifically to reporting adverse reactions to this drug.

Report an adverse event.