Editor's note: This English translation was done by a third party. The original report can be accessed here.

French Agency for the Safety of Health Products (ANSM) November 30, 2022

Finasteride 1 mg (Propecia and generics): added warning statements on boxes to reinforce information on adverse effects

As an extension of our actions aimed at strengthening patient information on the potential adverse effects, in particular psychiatric and sexual, of medicinal products containing finasteride 1 mg, and on the disclosure of these effects, we have asked the manufacturers to affix an alert message, accompanied by a QR code, to these medicine boxes.

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

- A red box indicating that sexual and/or psychiatric adverse reactions may occur during and after treatment;
- A QR code that links to our thematic file <u>Finasteride 1 mg and hair loss</u>.

At the same time, the information sheet intended for patients to make them 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 indicated in mild forms of alopecia (baldness) of androgenetic origin in men ages 18 to 41 years.

Information for patients

Finasteride can cause adverse drug reactions (ADRs), in particular psychiatric and sexual ones, the impact of which can be significant. It is essential to know these ADRs before starting treatment, and to be monitored throughout the 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 your reporting, you can consult our video devoted specifically to reporting adverse reactions to this drug.

Report adverse reactions.