Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) December 10, 2019

Editor's note: This English translation from the French text was done by a third party. The original patient-information leaflet can be accessed at <u>ANSM.sante.fr</u>

Information for Patients

Finasteride 1 mg (Propecia and generics) for hair loss General Information

Finasteride 1 mg (Propecia or generics) is used to treat some mild forms of hair loss (androgenetic alopecia) in men ages 18 to 41. Finasteride inhibits the transformation of testosterone into dihydrotestosterone (DHT), a hormone that can reduce hair growth and hair volume.

Its intended effects usually occur 3 to 6 months after starting treatment, and often fade 6 months after stopping treatment. In a study of more than 1,000 patients with mild to moderate hair loss, 65% of them showed improvements while on finasteride, and 37% while on a placebo, after one year of treatment.

Like all medicines, finasteride can cause side effects that you should be aware of before starting treatment. During the initial appointment with your doctor, do not omit any of your medical history (diseases, anxiety disorders, depression, etc.) or any current treatments, because they could signal concerns about prescribing finasteride in light of possible adverse reactions. It is important to discuss alternative solutions to finasteride as well.

Finasteride must be taken continuously to maintain its intended effect, so give yourself time to think before starting treatment.

What Are the Adverse Effects of Finsateride?

Sexual Disorders

By inhibiting production of DHT, which in humans is chiefly responsible for the development of sexual characteristics (hair, muscle mass, etc.) as well as fertility, finasteride can induce adverse effects.

Patients have reported sexual disorders including erectile dysfunction, ejaculatory dysfunction, testicular pain and decreased libido. These effects may persist after stopping treatment for an indefinite period.

Psychiatric Disorders

Psychiatric disorders may also occur during finasteride treatment, such as anxiety, depression or even suicidal thoughts.

All these disorders can have an impact on your social life.

Additional Adverse Effects of Finasteride

Other side effects may also occur during treatment with finasteride. You will find the complete list on the medicine's package leaflet. But you should be particularly aware of the following side effects:

- allergic reactions such as hives and itching of the skin;
- an increase in the sensitivity and volume of the breasts.

Very rarely, breast cancer has been observed in men treated with finasteride. To date, however, it has not been confirmed that finasteride is responsible for this cancer.

Action to Take in the Event of Adverse Effects

If your mood changes (feelings of sadness, anxiety, fatigue, difficulty concentrating, etc.), stop treatment yourself and consult your doctor.

If you experience any sexual problems or other side effects, report them promptly to your doctor. On such occasions, you can discuss with him continuing treatment or stopping it permanently.

If you experience swelling of your lips, face, tongue, or throat, or if you have difficulty swallowing or breathing, you should stop taking the medicine and contact emergency services immediately ([via French 911 equivalents] 15 or 18) as it may be an allergic reaction that may progress to anaphylactic shock.

How Long Do Adverse Effects Last?

The time it takes for adverse events to set in during finasteride treatment may vary, from a few days to a few years after starting treatment.

The duration of the adverse effects may also vary widely from patient to patient. Adverse effects may persist after stopping treatment, and in some cases for an indefinite period.

Drugs containing finasteride 5 mg also exist. They are prescribed for the treatment of enlarged prostate. In no case should you take finasteride 5 mg for hair loss.