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Propecia, Prescribed to 30,000 Men to Combat Hair Loss, Is on the Hot Seat. Doctors Issue Alert By Elsa Mari

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

For the first time, the National Agency for Drug Safety (ANSM) has issued an alert on the risks associated with finasteride. The agency will inform health professionals today at a meeting of the National College of General Practitioners.

Objective: to warn patients about this drug that treats enlarged prostate, especially among seniors. But finasteride, at a smaller dose, also reduces hair loss in younger men. It has been marketed under the name of Propecia since 1999.

Except that this miracle pill, which is prescribed to 30,000 patients and blocks normal testosterone production, precipitates side effects.

"Cases of depression and suicidal ideation have been reported, in addition to the already known sexual disorders. These effects are not proven, but the precautionary principle applies," says Dr. Caroline Semaille, director of anti-infective drugs, hepatogastroenterology and dermatology at ANSM.

The message is clear: in case of psychiatric symptoms, stop this medication immediately and consult a doctor as soon as possible. The ANSM warning comes in the wake of the European Medicines Agency listing adverse drug reactions to Propecia, which is marketed by Merck. The pharmaceutical company did not respond to our request for comment.

## Increased Risk of Depression

It was the publication of a study reassessing the risks of finasteride that pushed the EMA to take more precaution. This Canadian survey of 93,000 men over the age of 66, published in May, showed an increased risk of depression in patients taking finasteride because of their prostate.

"As finasteride contains the same ingredients as Propecia, we obviously took into account these results," says Dr. Semaille.

ANSM has also looked closely at reports of adverse reactions to finasteride in France. There have been forty such reports in nearly twenty years. And those numbers are not taken lightly.

"We know they are undervalued, because France does not have much pharmacovigilance reflex," says Dr. Semaille. And, worldwide, 508 serious psychiatric cases, including 25 suicides, have been identified.

The agency also mentions extremely rare reports of breast cancer in humans.

"The Scandinavian countries are responsible for doing a study for Europe. They should deliver their findings by 2019," says Dr. Semaille.

According to François Desgrandchamps, head of the urology department at Saint-Louis Hospital in Paris, "Gynecomastia men taking this drug is proven. Regarding side effects, he asserts: "I will not be against the prohibition of Propecia. If it were me, I wouldn't take the drug."

## 2012 Group Action in the United States

The controversy over this product has grown steadily. In 2012, a class action against the drug was launched in the United States. A hundred Frenchmen have also come forth to report serious sexual disorders, which are sometimes irreversible.

The original clinical trials for finasteride, however, specified that only 1% of patients experienced adverse reactions, and those disappeared after stopping treatment, which patients now deny.

Compounding these health concerns is that Propecia is used only for aesthetic purposes, not medical. Dr. Semaille has been vocal about this fact, which is why ANSM has launched it information campaign. The agency is essentially saying to men, "From now on, you are informed, so you decide."