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Finasteride (Propecia and generic versions): A dangerous, not very effective, product

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Prescribed for young men with mild hair loss/baldness, finasteride, which acts by blocking a hormone responsible for hair loss, is only marginally effective. Now that there is a fairly large knowledge base documenting its serious side effects—depression, suicidal ideation and sexual problems that potentially persist after ending the treatment—health authorities have still not pulled it off the market.

I understand, hair loss is a real drag. I can prescribe finasteride for you, and you’ll have approximately 10% more hair growth on top of your head. However, you should know that you risk experiencing depression, which can lead you to commit suicide. Ah, I was forgetting: you also risk a loss of libido and problems getting an erection, as well as problems with ejaculation. You may then of course stop the treatment, but the sexual issues could persist. So you’re in? Shall I write you the prescription?

This is the rather surrealistic monologue we imagined after reading the letter sent by ANSM, the French National Agency for Medication Security, to health professionals likely to prescribe or sell finasteride. Reminding them of the psychological and sexual side effects of this product, the agency concludes that if a patient is there because he is losing his hair, “It would be wise to discuss the risk-benefit relationship of the product with him.”

Finasteride’s active ingredient was first used in benign hypertrophy (swelling) of the prostate, with a recommended dosage of 5 mg per pill[1]. Since 1999, however, it has also been offered to young men at a dose of 1 mg per pill, to treat androgenetic alopecia, also known as hair loss. It was sold under the brand name of Propecia, and several generic forms of the drug are also on the market[2]. It blocks the production of a hormone called DHT, which is responsible for this kind of balding. Its effectiveness remains limited: the drug only works on about half the patients taking it, and it only increases hair growth on the top of the head, not on the temples or sides. Users noticed only 11% increased hair growth after a year, which remains stable only if treatment is continued; hair loss begins again if treatment is stopped.

Disagreement on the Risk/Benefit Relationship

Notwithstanding these rather poor results, finasteride has had a certain success with young men with hair loss (30,000 boxes sold in 2012, the last available sales numbers). But this drug is hardly innocuous. Sexual side effects were reported even in the first trials evaluating the drug’s effectiveness. Since then, more have been reported over the years and with the re-evaluations ordered by the health authorities of different countries. Anxiety, depression, suicidal ideation, serious muscular pathologies, allergic reactions, male breast cancer, the persistence of sexual problems after stopping treatment—there are so many side effects linked to this drug. The ones cited by ANSM, which drew the attention of health professionals, psychiatric issues and persistent sexual dysfunction—were considered “infrequent,” but it does indicate a frequency between 1/100 and 1/1000 users, which is not insignificant. Especially since, according to a
meta-analysis of recent clinical studies, the evaluation of adverse effects is incomplete. A study of more than 4,000 young men showed that 0.8% of them reported persistent erectile dysfunction, with a median length of more than 4 years! Nonetheless, ANSM continues to assert that the risk/benefit relationship of this product is favorable.

An Association to Help the Victims

That decision is incomprehensible to Sylviane Million-Mathieu, whose 25 year old son took his life in June 2016, a suicide she attributes—"a full set of lab tests in hand"—to the hair-loss medication. The association she founded, Help for Victims of Finasteride, claims 200 French members and a similar number from other European countries. Along with its discussions with health authorities, the association has hired the prominent lawyer Charles Joseph-Oudin, a health-law specialist who also went up against Mediator and Dépakine, to represent it in court.

“We are building sixty cases, but for the moment we are issuing a summons to MSD, the lab which sells Propecia, for four of them,” explains the lawyer. “We’re asking for the appointment of experts in endocrinology and andrology to confirm the causality between taking this drug and the psychiatric and sexual issues, as well as the persistence of adverse effects. From our point of view, the laboratory was aware of these side effects for years and did not report them to either patients or practitioners. We have a twofold goal: the improvement of the information delivered to patients, and compensation and comprehensive care for the victims.”

While awaiting a withdrawal from the market recently evoked by the independent magazine Prescrire, ANSM appears not to be ready [to do the same thing]. “Whatever the frequency and seriousness of the side effects, the Agency has a marked tendency to conclude that the risk/benefit relationship is favorable,” laments epidemiologist Catherine Hill. “And it has, to my knowledge, not written a word touting the drug’s benefits.”

Which makes sense, since there aren’t any. And if there are, they’re not medical but aesthetic. In any case, the agency, which we have asked for its basis in this evaluation, did not deign to answer us. Do they not have the time? We will give them the benefit of the doubt and will update this article as soon as the ANSM has justified its position.

(1) Given its side effects, the magazine Prescrire advises limiting use of the product as it is prescribed.
(2) Their names all use the word “finasteride,” except Finhair Gé.