

**Starbene (Italy)
August 2019**

Editor's note: This English translation was done by a third party. The original digital story can be accessed [here](#).

With this Hair-loss Medication Comes Great Risk

It's finasteride, and it contributes to hair growth in men. But it can cause a syndrome leading to impotence, loss of libido and even depression. This is what we uncovered.

by Adriano Lovera

The entire world, including Italy, is experiencing a tragedy that requires our attention. It's that of men, often young, who in hopes of treating their hair loss, experience much more serious issues after a number of years: erectile dysfunction, loss of libido, sleep problems, even anxiety and depression—so serious in some cases as to lead them to commit suicide. These are tragedies that end up ruining the lives of entire families. As the mother of a 25-year-old, who decided to write to our editorial staff, says, "I'm defenseless against this condition. My son has been in a black hole for a good five years, without any way out." Following her letter, we decided to investigate.

From the prostate to alopecia

Finasteride was conceived and produced in the 90s in the United States by Merck, and reached Italy in 1999. It's a drug with a unique history. It debuted as Proscar, and is used by andrologists and oncologists, in doses of 5 mg, to treat enlarged prostate. But it soon came to light that the drug also helps with hair growth. So, after some years, the drug appeared in 1 mg for, as Propecia, prescribed by dermatologists for the most common form of hair loss, androgenetic alopecia.

"This drug, which has an effect on a specific enzyme, reduces the levels of DHT, a hormone that's among those responsible for the increase in the size of the prostate, but also for the atrophy of the piliferous follicle. An effective drug," says Roberto Cosimo Melcangi, professor of endocrinology at the department of pharmacological and bio-molecular sciences at the University of Milan, who has been conducting studies on the issue for years.

"The problem is that this alopecia therapy is often recommended even prior to 20 years of age." And the unluckiest of these young people fall into a spiral in which it becomes impossible for them to lead a normal life. The American PFS Foundation (acronym for post-finasteride syndrome) notes that the World Health Organization already reviewed more than 15,000 cases of adverse reactions to finasteride, 23% of which are psychological issues, 19,5% erectile dysfunction, 12% libido issues, and 10% cases of anxiety and depression. "My team in Italy, over the years, has received about 100 reports. We already published three clinical studies and are able to estimate a PFS incidence rate of 3% to 4%.

The WHO collected 15,000 cases of adverse reactions to the drug. In Italy, the number of patients who reported adverse reactions exceeded 100," Melcangi adds.

The patients' battle

But it's not enough. Among virtually all other drugs, side effects appear during the period of intake, and they disappear after therapy is interrupted. With finasteride, this is not so. "This is the real obstacle. In the cases of those whose side effects remain persistent for a number of years, we categorize them as PFS," Melcangi explains.

Over time, as the number of clinical studies has increased, patients suffering from the condition have been identified all over the world, including in Italy. Meanwhile, the drug's package insert has been updated to include "suicidal ideation" among its rare side effects. In the United States, Merck is involved in several class-action lawsuits for having failed to suitably inform patients of all possible adverse side effects.

"We entrusted in-depth studies to experts, and after the summer, will be ready to file some lawsuits. In a criminal investigation, the possible offenses would have passed their statutes of limitations. But civil reparations are possible," says attorney Laura Cagnin, from the Calvetti law office, which is working with the Association of Victims of Finasteride. "The majority plaintiffs assisted by us, about 20 of them, have taken the drug in the past decade and they are still suffering the consequences today." In Italy, Propecia is produced by MSD Italia, a subsidiary of Merck & Co., which tells us: "MSD fully supports the value of Propecia, prescribed to millions of men since its approval. As with all drugs that are subject to medical prescription, the package inserts correctly inform the patient and the physician of all of the advantages, risks and adverse reactions. Nothing is more important for MSD than the safety of its own drugs and of the persons using them. We encourage patients to talk with their family physician with regard to any doubts or questions relating to their health."

Is it possible to recover from the syndrome?

Unfortunately, there is no way to "go back" and return one's body to the state it was in prior to using the drug. "Many studies have been carried out by now, but we still have not succeeded in even precisely defining post-finasteride syndrome. It will take years," Melcangi adds. "The good part is that nowadays many dermatologists are aware of the risks and, as a result, they are more cautious when prescribing the drug. Those who suffer from the condition should speak to an andrologist or psychologist, based on the type of side effects. It's essential not to give in to the temptation of trusting some forum that recommends do-it-yourself therapies. There is a risk of causing even more damage."

AIFA (Italian Medicines Agency): 17 cases in the past 2 years

The last action by the Italian Medicines Agency (AIFA) concerning finasteride dates back to July 2018. It is an "important note" of pharmacovigilance that encouraged physicians to be aware of the drug's risks prior to prescribing it. The annual number adverse reactions recorded by AIFA has remains steady, at 17, over the last two years. But is there a predefined numerical threshold, beyond which a drug should be taken off the market? "No, we evaluate on a case-by-case basis and it depends on the type of reaction," the agency tells us. "If the pathologies caused by a drug are very rare relative to the entire population, even very few cases are enough to generate a warning. If it instead concerns frequent occurrences, the number of cases must be greater."

And, at least at this time, finasteride falls within the latter category, considering that it is difficult to ascertain with certainty whether the more common reactions were not already present in the patient even prior to the therapy, perhaps in a latent state.