

L'OBS

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Propecia, this anti-hair loss drug accused of ruining lives.

Romain, 25, committed suicide in June 2016. The fault, according to his family, the "post-finasteride syndrome", the name of the molecule of this treatment against hair loss. The American laboratory Merck and Co, which markets it, could be prosecuted in France.

It is a banal appointment with the dermatologist of the family. At 19, Romain loses a little hair. "There is a great thing without side effects, all young people take it," recommends the specialist. Its name? Propecia, a drug manufactured by the American laboratory Merck & Co.

In October 2010, Romain Mathieu began to ingest the octagonal and orange tablets daily. At first, he goes through periods of great fatigue, he also has problems with erection and sleep. Six years later, comes impotence. He vomits fifteen times a day, does not sleep at night, loses his memory. Romain commits suicide on June 7, 2016. He is 25 years old. In his farewell letter, he writes: "I will strive to die with a smile, like a last snub to this disease that I will escape".

Hundreds of testimonies overlap. All come from men who tell a nightmare. After taking Propecia or dozens of other medicines with a common active molecule, finasteride, they report severe sexual, cognitive, and physical problems that persist long after treatment has stopped. Their trouble, they name it "post-finasteride syndrome".

This trouble is not recognized. In the United States, and in Canada, nearly 2,000 victims gathered to sue the Merck & Co laboratory (see below), which first commercialized the Propecia in 1997.

Despite the warnings issued by health institutions in various countries, including France, and several disturbing changes in the leaflet (see below), in our country, finasteride is included in 23 generic drugs produced by 16 laboratories. Doctors, generalists or specialists, prescribe this molecule without restriction.

For a box of 28 tablets, to be taken daily, dosed with 1mg of finasteride, Propecia is sold about 50 euros and generics between 15 and 20 euros. None are refunded. Its efficiency – purely aesthetic – is limited. In the studies that were used for its marketing authorization, in 1999, patients had an 11% increase in the number of hair but only on the top of the skull.

Efficiency is not proven on bitemporal gulfs, above the front. In addition, a new hair-loss appears when the treatment stops. In addition, the study lasted only 24 months, so it does not focus on long-term effects. Finasteride, the active molecule of Propecia, has also been used in the 5 mg dosage since 1992 to treat the adenoma (swelling) of the prostate.

In all, nearly 128,000 French people were exposed to the substance in 2016. The National Agency for the Safety of Medicines and Health Products (ANSM) reported the sale of 11,141,228 finasteride tablets of 1 mg, and of 35,617,456 tablets of 5 mg.

Six years of struggle

Sylviane and Marion, Romain Mathieu's mother and little sister, welcomed us in an old-fashioned, mothballs light-smelling house, just a stone's throw from the village of Orgeval (Yvelines), which they left for the Côte d'Or since the suicide of Romain. Sylviane, 51, has a determined look under her brown bangs: very warm, she often laughs. Marion, 24, is more discreet. She often completes her mother's comments. It is in two voices that they relate the six years of struggle of their son and brother against the "post-Finasteride syndrome" ignored by medicine.

At the end of 2010 when Romain begins to feel his first difficulties, no health professional worries. The young man has integrated a preparatory class HEC, a sector of excellence. "It's just stress," evacuate the GPs and his dermatologist without answering Romain's concerns, who finds that his disorders occur in increasingly long and intense waves. Sylviane accompanies her son to all the consultations. She remembers the names of all the doctors: "I had warned doctors that Romain was taking a medicine against hair loss, but no one told us that it was not good."

Two years later, Romain is alarmed. A hard ball develops on one of her breasts. The young man makes an appointment at the Lariboisière hospital in Paris. For the first time, he is prescribed exams. "I must have the results somewhere," murmurs his mother who has filed all the prescriptions and exams in a huge binder on the dining room table. The results of the first exams are very worrying.

Romain suffers from disorders of the liver and spleen. He is deficient in protein and vitamin D. His testosterone, the male hormone, is 0.38 ng / mL, that of an impotent old man. Many doctors see these results: they are troubled, but do not understand, and do not try to understand. It is a pharmacist who alerts Sylviane when she makes him read a prescription from his son. When she reads the word "Propecia", she ticks: "You do not give it to your son anyway? There are controversies around this medicine!"

More and more in difficulty, Romain embarks on internet research on this mysterious substance that could be at the root of his ills. He comes across a discussion forum, PropeciaHelp.com, and reads the many published testimonials. It is recognized by the symptoms described by these hundreds of people who all consume in one way or another finasteride, the active molecule of Propecia.

"It's sexual torture"

In April 2013, Romain interrupts his treatment. The symptoms stop. He's relieved, he's breathing. It only lasts a while. After two weeks of rest, he suffers like never before. The troubles he experienced reappeared with a power tenfold, accompanied by new disorders.

For this survey, we interviewed ten other men sharing the same sexual, physical and cognitive problems as Romain, but at different intensities. All say they suffer from "post-finasteride syndrome".

Gilles * (the name was changed), 31, stopped taking Propecia after three months, when he found a total lack of libido. Six years later, his symptoms still persist: "My penis has become pale, purplish, my penis has narrowed, I feel it has been torn from me, it is sexual torture." Met in a Parisian I, he compares his genital pains to a mutilation.

Peter * (the name has been changed), a thirty-year-old living in the UK, felt the first effects twenty minutes after having swallowed the third tablet of his life, last May: "I lost 3 pounds in one week. At first I could not get up, now I can walk, but I have to urinate fifteen times a day, and sleeping two hours a night is a luxury. "

Alexandre O., 39, from Paris, started Propecia in 1999, as soon as the drug was marketed in France. He quickly notices memory failures, panic attacks, social phobia: "Someone was telling me something, and an hour later I forgot, my colleagues thought I was doing it on purpose to get fired." He evokes an altered perception of reality: "I saw things around me as if I was looking at a painting, I was just a spectator of my life."

The causal link between these symptoms and the active molecule of Propecia is not scientifically established. The Northwestern University School of Medicine, however, published a study in March 2017 on a sample of 11,909 men who took finasteride: 1.4% (or 167 subjects) developed persistent erection disorders over a median time of three and a half years after stopping treatment. Another study from the University of Milan, published in July 2017, focused specifically on "post-finasteride syndrome". In 16 patients suffering after taking the molecule, the researchers found major depressive disorders and altered levels of neuroactive steroids, hormones related to the nervous system of the brain. Other studies are in progress.

A foundation in the United States

For now, the only certainty concerns the mode of action of the molecule. Finasteride blocks the action of an enzyme, 5-alpha-reductase, which converts testosterone into another hormone, DHT (dihydrotestosterone). However, it is the DHT that causes hair loss. But, problem: DHT also acts greatly on libido and fertility, and other biological factors.

Joined in the United States, the doctor John Santmann does not hide his anger. "By taking finasteride, you eliminate the effects of testosterone," says the specialist who created in New Jersey Foundation "post-Finasterid syndrome" following the suicide of his son. "You do not have to be an outstanding scientist to tell yourself that finasteride may not be a good idea, you ruin your body, and you do it for an aesthetic reason: it's totally crazy!"

In September 2016, the Foundation opened a victim support service. Its manager, Philip Roberts, a former journalist, responded to more than 1,000 requests for information. Including those of distraught doctors: "Two asked me for advice about their own symptoms, one in South Africa and the other in Delaware."

Despite his efforts, Dr. John Santmann's prejudices against Propecia did not reach Europe. In France, Gilles received no warning. "I asked my pharmacist clearly: are you sure there is no problem with the Propecia?" He replied, amused, "Of course not."

Like all the victims, Romain Mathieu, who became a student at a major Parisian business school, embarked on an exhausting quest for doctors. With his mother, they see thirty. "We lost time, and we received a lot of refusals from the doctors," Sylviane regrets. Practitioners do not understand the disease, sometimes they do not believe it: "When we came out, Romain punched the walls, he could not stand to be said 'At your age, such state, it's impossible.'"

Four years after the first troubles and two years after the discontinuation of the Propecia, Romain and his mother finally find a doctor who helps them: Dr. Gontier, in Mantes-la-Jolie, is a generalist adept in functional medicine. Unlike specialists, it does not focus on a specific symptom but on all disorders. Dr. Gontier prescribed to Romain advanced biological analyzes. Three months later, the results fall: the intestinal wall and the flora of the young man – two crucial cogs of the immune system – are badly damaged. Romain met two gut specialists, Jacqueline Warnet and Louis Berthelot. Today Dr. Berthelot monitors twelve patients who have taken finasteride: "The disorders are huge! And each patient reacts differently. Take care: I have a patient who can not have an erection but when we do the dosage testosterone, the rate is normal! That's why they are said to be crazy, but they are not crazy. Everything is not understood about these disorders, I assure you.

Does finasteride alone cause these disorders? Dr. Berthelot asked. "The molecule is directly involved, but I also believe that there is a notion of vulnerability in some people, as if you were cracking a match in the middle

of the forest, but not knowing if the wood, the twigs, and the leaves are wet or dry ...In one case, nothing happens. In another, everything burns ! “ And nothing stops the fire. Several improvements in Dr. Berthelot’s patients have been noted, but no complete remission for now.

Most men with “post-finasteride syndrome” do not have the chance to be monitored by a doctor. Most fend for themselves, exchanging advice on the internet. Gilles fasted for up to 40 days. Alexandre O. was gorged with vitamins, proteins, meditation, he tried sea bathing, massages, acupuncture, electrical stimulation ... Romain and Sylviane, his mother, were also ready for anything “It was my son, I would have gone to the end of the world for him, I even sent him to see a shaman in Thailand. “

“Either we fight or we collapse”

In 2015, the young man gathered his last forces to apply for a position in a merger and acquisition department in a merchant bank. The overwhelming workload, he hopes, will make him spend time faster. “Romain succeeded!” exclaims Sylviane proudly. The young man is hired by Deutsche Bank, one of the most prestigious banking institutions. He also advises his friends looking for jobs: “That’s what helped him to stay in sickness,” says his mother. But Romain understands in advance that he will not be able to get to his first day of work at the beginning of July 2016. Too tired, literally exhausted. Sylviane: “In the end, my son was banging his head against the walls so much he was in pain, he was so worn out that he could not go to the bank, which clearly contributed to his departure date. “

Romain feels that his forces are abandoning him. The young man prepares discreetly. He arranges his personal belongings in suitcases, his books in boxes. He half-mown the grass, and warned his sister that the mower was broken. “That was his last sentence, Romain left as he lived: doing the maximum,” says Marion.

At the death of Romain, Sylviane is involved in the fight against finasteride and support for victims. She had no choice, she said, “Either we fight or we collapse.” She spends her nights and days on Facebook, on the phone, hours and hours, without a break. “I regularly receive calls for help from young people who are likely to act.”

They also ask him to explain the disease to their relatives, unaware of the tragedy being played.

In the summer of 2017, Sylviane met the lawyers of the firm Dante, engaged in the trials of Mediator and Dépakine. Maître Charles-Joseph Oudin is currently working on a dozen victims’ files, and is calling on others to join him. “We hope to launch legal proceedings against the laboratory by the beginning of 2018, or in the spring. These will be individual actions that can be joint.” For now, the goal is to establish the causal link between the molecule and the pathology in each file.” We can then decide to launch a criminal procedure, if we have the elements that justify it; or seek only compensation. “

Along the judicial part, Sylviane founded, in September 2017, with the father of another young victim, the association AVFIN, for “ Assistance to Victims of Finasteride “, whose aims are to inform patients and doctors, obtain recognition for the victims and allow them access to care. Finally, Sylviane is in regular contact with the ANSM. She keeps alerting its agents about the situation of victims, and most importantly, she tries to trace as many cases as possible to pharmacovigilance, the device for detecting adverse drug effects. “It’s horrible, but the more suicides there are, the more we’ll talk about it,” Sylviane believes.

At the ANSM, Dr. Caroline Semaille, director of the department in charge of dermatology, recognizes: “If patients do not declare their case, we can not be aware of the side effects felt and we can not do anything.”

In April 2017, the European Medicines Agency recommended replacing “depressed mood” with “depression”, and adding the risk of “suicidal ideation” in drug leaflets containing finasteride. These changes were the subject of an information note from the ANSM on October 26, 2017. “No one forces patients to take

finasteride, adds Caroline Semaille. The important thing is that they can decide by having knowledge of these risks “.

Precisely, to inform on the risks of depression and suicidal ideas is it enough? According to our survey, the symptoms of the victims encountered go far beyond. According to the pharmacovigilance data too. The ANSM reports 45 cases of disorders following exposure to finasteride reported in France, including three asthenia (intense fatigue), two insomnia, one of cognitive disorders, one of abnormal behavior, and suicide .

Despite all these unexplained risks, and despite the purely aesthetic and limited benefit of finasteride, the European Medicines Agency stipulated in April 2017 that the benefit / risk ratio of Propecia “remains unchanged”, that is to say favorable .

This opinion of the authorities, the MSD laboratory, a French subsidiary of Merck & Co, did not fail to remind us. In a written answer to our questions, they added: “We pay the utmost attention to the quality and safety of use of our medicines. We are confident in the rigor of scientific studies that have allowed to develop [the Propecia 1 mg]. “

While waiting for possible counter-studies, Sylviane has her own way of informing about Propecia. She plays a funny part. Claiming that his son is losing his hair, that he does not see it well, she makes an appointment with a specialist. “It’s hard as a game,” she breathes. It happens that the specialist offers finasteride “without any side effects.” “Oh ...?” Sylviane listens patiently to the explanations, and in the end she lets go: “I’m Romain Mathieu’s mother. My son committed suicide because of finasteride, I can give you many other names of young people who are at risk of leaving or who have already left. “

You have taken finasteride and you think you are suffering from side effects?

It is important that you declare your case for pharmacovigilance. Consult your doctor and go report to this website: solidarites-sante.gouv.fr

Changes in the leaflet

In France. In 2009, ten years after the Propecia was placed on the market, the mention "persistent erectile dysfunction after stopping treatment" is added to the package leaflet. In 2010, the "risk of breast cancer in humans" is added.

Two years later, the National Agency for Health and Medicine (ANSM) publishes an information point, stressing that "finasteride is subject to particular vigilance at European level".

In Europe. In April 2017, the European Medicines Agency recommended changes in the leaflets for all finasteride-based medicinal products in the 31 countries of the European Economic Area. Manufacturers must replace "depressed mood" with "depression", and add the risk of "suicidal ideation". The French ANSM waits six months to publish, on October 26, a point of information about these new changes.

In the USA. In April 2012, the Food and Drug Administration, the drug agency, requires to mention many side effects that may persist after stopping the drug: libido disorders, erection, ejaculation, orgasm, risks of infertility and / or sperm quality decline, which fade or cancel after stopping treatment.

In New Zealand. In 2016, the Pacific Island is the first country to recognize that "post-finasteride syndrome may affect some men who have taken finasteride", including physical, mental and neurological effects, persisting after stopping treatment.

In South Korea. The authorities impose the mention of depression and suicidal ideation.

Class actions

1,300 victims of finasteride filed a case in the United States against Merck, which they accuse of not having informed them about the persistence of side effects before 2012: what is called a class action. This group action allows individuals to collectively bring a lawsuit to assert their rights or their prejudice. The procedure is possible in France since January 2016, provided that the plaintiffs gathered in association: 2,000 families of victims of Depakine (a drug prescribed to pregnant women and accused of rendering their child autistic) have used for the first time this legal tool in December 2016, before the Tribunal de Grande Instance of Paris.

The trial against the Merck laboratory first scheduled in the US in the fall of 2016 was postponed for the first time to September 2017. It should finally be held in February 2018.

In Canada, two similar class actions are in progress, involving nearly 500 victims.

"One morning, my sex did not work anymore"

Gilles' ordeal, treated with Propecia

In March 2010, the 25 year old man takes Propecia against the fall of his hair. Even today, he says he is suffering from side effects.

"One morning, it did not work anymore, I felt that my sex was no longer working, it was very brutal."

We are in March 2010. For three months, Gilles (the name has been changed) takes Propecia, manufactured by the American laboratory Merck & Co, to curb his hair loss. The young man, then 25, a chemistry student, immediately suspects side effects.

He rushes to internet. On forums, he discovers hundreds of testimonials where he recognizes himself. After taking finasteride, the active molecule of Propecia, men say they have lost their sex life, can no longer have erection, pleasure. "I thought, 'What did I do damn?'"

He will not swallow any of these octagonal orange pills anymore, but it's too late. Today, six years after he stopped Propecia, he is at his worst. "It's mutilation, I feel like I got my sex torn apart." His sexual pains are accompanied by mental disorders. "This disease robs you of your personality, everything that you are passionate about, you do not feel love any more, I could have put an end to women relationship, but I can not even have an intellectual activity."

He has trouble concentrating, memorizing, especially in the short term. He can hardly read. In fact, Gilles often sells his days watching videos on the internet. Impossible to work, even to leave home. He is anxious. He lives from social subsidies. "In the morning, I do not want to open my eyes anymore."

Living alone, Gilles often remembers, with bitterness, the first tablet he swallowed. He is angry at his dermatologist. "He prescribed it without warning - except for a possible loss of libido," says the young man. Same scenario in the pharmacist. "I asked him clearly: 'Are you sure there is no problem with Propecia?' He replied, amused, 'Of course not.' "

The two practitioners do not tell him that the molecule acts on hormones. "I would not have taken it otherwise, and in hindsight I feel like I'm in a trap." Because finasteride blocks the production of DHT, a hormone derived from testosterone, and responsible for hair loss ... But which also greatly affects sexual activity, fertility, and other biological factors.

Faced with the thirty doctors he saw later, Gilles is disappointed. Neurologist, infectiologist, urologist ... "They do not listen, they do not try to look beyond consultation." He browses among forums like PropeciaHelp or SolvePFS to find a cure: fasting, diets, immunotherapy ... "I fought beyond the possible," he says. At one time, Gilles had also joined a group of victims to discuss the disease regularly.

At the end of our interview in a Parisian cafe, Gilles sees a person with a very bald head, leaning on the counter: "You see, today, I would be happy to be bald."

To be read in our survey

Hundreds of men around the world report a plight similar to that of Gilles. We interviewed ten. After taking finasteride at 1 mg, these individuals experienced severe sexual, cognitive and physical problems that persisted after discontinuing treatment. They say they suffer from an unrecognized trouble: the "post-finasteride syndrome". In all, nearly 128,000 French people were exposed to the molecule in 2016. In France, the substance is used in 23 generics produced by 16 laboratories. In addition to hair, it is also used in the treatment of adenoma (swelling) of the prostate, at a dosage of 5 mg.

Precautionary opinions have been issued by health institutions in several countries, including France. Since June 2017, the leaflet mentions the risks of "depression" and "suicidal ideation". Some doctors worry about the side effects of finasteride. But despite risks still largely unexplained, and despite a purely aesthetic and limited efficiency, the European Medicines Agency stipulated in April 2017 that the benefit / risk ratio of Propecia "remains unchanged", that is to say, favorable.

In the United States, and in Canada, nearly 2,000 victims have already gathered to sue the Merck & Co laboratory, which first commercialized the Propecia in 1997.

In a written answer to our questions, MSD, the French subsidiary of the Merck & Co laboratory, states: "We pay the utmost attention to the quality and safety of use of our medicines. We are confident in the rigor of studies scientists who have developed [Propecia 1 mg]. "

In France, victims began to mobilize to file a complaint in 2018. Their lawyer, Charles Joseph-Oudin, calls others to join him. Sylviane Mathieu, whose son committed suicide as a result of the side effects caused by Propecia, has just founded an association: AVFIN, for "Assistance to Victims of Finasteride".