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

**Italian Drug Agency**

**Safety Communication**
**Finasteride 1 mg: possible sexual and psychiatric disorders**
**Nov. 30, 2022**

The Italian Drug Agency (AIFA) draws your attention to this important safety information concerning medicinal products containing finasteride 1 mg, indicated for the treatment of androgenetic alopecia:

Summary

• There have been case reports of patients experiencing:

—sexual disorders, including erectile dysfunction, ejaculatory dysfunction, testiclular pain, and decreased libido;

—psychiatric disorders, such as anxiety, depression or even suicidal thoughts. All of these disorders can have a major impact on your social and personal life.

• The time to onset of the above symptoms can vary, from a few days to a few years after starting treatment. The duration of adverse effects can also vary widely from patient to patient. Adverse effects may persist after discontinuation of treatment and, in some cases, indefinitely.

• After careful diagnosis of androgenetic alopecia, before making a therapeutic decision, it is recommended to:

—acquire a complete medical history that includes any information on both physical and mental illnesses (eg anxiety disorders and depression), and information on any current treatments (medicines, supplements, etc.). The importance of collecting information on any psychological difficulties is underlined because, with the assumption of finasteride, psychiatric symptoms could occur, which could in turn aggravate existing conditions;

—discuss with patients the expected benefits of treatment with finasteride 1 mg, and the potential risks, with particular reference to the possibility of sexual disorders and/or psychiatric disorders occurring, and that these events, in some cases, may persist even after discontinuation of therapy.

• It is important that patients are adequately instructed to seek immediate medical attention at the first sign of symptoms of sexual disorders and/or psychiatric disorders.

• Patients should be closely monitored and discontinuation of treatment is recommended if the above symptoms occur.

These recommendations apply to the 1 mg strength indicated for the treatment of androgenetic alopecia.

Basic information

The benefit-risk ratio of the active ingredient finasteride is subject to constant and careful monitoring, both at European and national level. At present, this ratio is considered favorable in the authorized indications. This safety communication joins those previously issued by the Italian Drug Agency and published on the institutional portal:

• November 2017: Finasteride 1 mg containing medicines: new safety information regarding rare cases of depression or suicidal ideation.
(https://www.aifa.gov.it/documents/20142/241044/IT_NII_finasteride_1_mg_29.11.2017.pdf)

• July 2018: Possible risks of sexual dysfunction and psychiatric disorders with medicinal products containing finasteride 1 mg and recommendations to inform patients.
(https://www.aifa.gov.it/documents/20142/0/Nota_Informativa_Importante_Finasteride_30.07.2018.pdf)

The active ingredient finasteride acts by inhibiting the miniaturization process of hair follicles in the scalp, making the baldness phenomenon reversible; this action is due to the inhibition of the transformation of testosterone (a male sex hormone) into dihydrotestosterone. However, hair loss can have a different origin than androgenic origin, i.e. it can be the result of psychological stress, iron or vitamin deficiencies, illnesses, or the intake of certain othet medicines. In such situations, taking finasteride 1 mg would have no effect on hair loss and would only expose the patient to adverse events.

Further information is available in the Summary of Product Characteristics of the medicines covered by this communication.

Invitation to report adverse reactions

Healthcare professionals are reminded to report suspected adverse reactions associated with the use of medicinal products to the national competent authorities in accordance with the national spontaneous reporting system. More information can be found on the agency portal at the following link: https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse

AIFA takes this opportunity to remind all Healthcare Professionals of the importance of reporting suspected adverse drug reactions, as an indispensable tool for confirming a favorable benefit-risk ratio in real conditions of use.

Reports of suspected adverse drug reactions must be sent to the Pharmacovigilance Manager of the Facility to which the Operator belongs or alternatively they can be made via the online reporting system https://servizionline.aifa.gov.it/alertstab/#/

This communication is also published on the AIFA website (www.aifa.gov.it) whose regular consultation is recommended for the best professional information and service to citizens.