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Italian Drug Agency (AIFA)
November 29, 2017

IMPORTANT NOTICE ISSUED BY THE ITALIAN DRUG AGENCY

Medicines containing finasteride 1 mg: new safety information concerning rare cases of depression or suicidal ideation

Dear Operator / Healthcare Operator / or (Name of the Marketing Authorization Holder) of the medicines containing finasteride 1 mg indicated for the treatment of androgenetic alopecia.

In accordance with the Italian Drug Agency (AIFA), we wish to inform you of the following:

• There have been reports of depression and/or suicidal ideation with use of medicines containing finasteride 1 mg, indicated for the treatment of early states of androgenetic alopecia in men ages 18 to 41.

• Healthcare professionals should closely monitor patients taking medicines containing finasteride 1 mg and, in case of symptoms of depression and/or suicidal ideation, recommend that the treatment be stopped.

• Patients and their caregivers should be advised to inform the prescribing physician in cases of altered behavior or mood, or the onset of depression or, signs/symptoms of suicidal ideation.

• Procedures for editing literature containing finasteride 1 mg to include these warnings are included here.

Additional information about this security issue

• The European periodic review of the benefit/risk (b/r) profile of medicines containing finasteride (PSUSA procedure) was completed in April 2016. The b/r profile of medicines containing finasteride remains positive. Furthermore, at the conclusion of the revaluation procedure, the Committee of Pharmacovigilance Risk Assessment (PRAC) asked the companies holding the marketing authorization for finasteride-containing medicines to review all available data from the date of their first authorization regarding any cases of depression and events related to suicidal ideation.

• The PRAC also concluded that the evidence supporting a causal relationship between use of finasteride 1 mg in alopecia and depression were rather limited. This is due to the difficult interpretation of spontaneous cases reported, as well as to the characteristics of the treated population that can be more prone to the occurrence of psychiatric disorders than the general population. However, taking into account the possible mechanistic explanation and the reported cases, the PRAC considered that there was sufficient supporting evidence to settle on at least one possible relationship between depression and finasteride 1 mg. Therefore, the Committee recommended adding "depression," with "unknown" frequency, in the product information as a possible side effect.

• Furthermore, since the PRAC does not consider the indication for use a "serious" condition, the PRAC considers it important that HCPs and patients should be fully aware of the possibility that treatment with finasteride 1 mg may be associated on the onset of depression and therefore also recommended the inclusion of a warning in the product information to inform that cases of mood alterations have been reported, namely depression and suicidal ideation, with the use of finasteride 1 mg. Also, monitoring of patients for any psychiatric symptoms and subjects being

treated should be reminded to promptly seek medical advice should any changes in behavior or mood arise.

• The PRAC did not consider that further action, in addition to the modification of the printouts, should be taken on the matter discussed here.

• Finally, the analysis of the data presented by the companies for the cumulative review requested by the PRAC were analyzed and included in the CMDh decision ratifying the PRAC recommendation. Therefore, the frequency of the ADR was changed from “not known” to “uncommon.”

Information on medicines containing finasteride

Finasteride is a type II 5-alpha reductase enzyme inhibitor drug that converts testosterone in the more active steroid dihydrotestosterone (DHT). Finasteride is used for treatment of benign prostatic hypertrophy and anhydrogenetic alopecia in males. DHT bears the greatest responsibility for the atrophy of hair follicles in men. Inhibition of its synthesis hormone can slow down the hair-loss process in men and, in some cases, stimulate regrowth of hair.

The dosage authorized for the treatment of alopecia is lower than that used for the others pathologies (1 mg / day versus 5 mg / day). The onset of depression was already listed among the reactions of adverse events associated with the use of medicines containing finasteride 5 mg.

Finasteride 5 mg was authorized in 1992 in Europe for the treatment of prostatic hypertrophy, while the authorization in the dosage of 1 mg for the treatment of androgenetic alopecia dates back to 1998.

Invitation to report

Healthcare professionals are reminded to continue reporting any suspected adverse reactions associated with the use of this medicine through the AIFA National Pharmacovigilance Network with the use of the following link: directly online on the website http://www.vigifarmaco.it or by following the instructions at the link http://www.aifa.gov.it/content/segnalazioni-reazioni-avverse

AIFA takes this opportunity to remind all Healthcare professionals of the importance of reporting of suspected adverse drug reactions, as an indispensable tool for confirm 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 proper department. This important information, which is also published on the AIFA website (www.agenziafarmaco.it)
Regular consultation of that content is recommended to maximize professional and services and best information to public of important health issues.