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

Peruvian Ministry of Health
General Directorate of Medicines, Supplies and Drugs

DIGEMID ALERT Nº 09–2018
FINASTERIDE: RISK OF MOOD ALTERATIONS, DEPRESSION AND SUICIDAL IDEATION

The General Directorate of Medicines, Supplies and Drugs (DIGEMID) of the Ministry of Health informs health professionals, institutions, pharmaceutical establishments and the general public that a modification of the insert and technical sheet has been arranged in the ADVERSE REACTIONS sections.

WARNINGS AND PRECAUTIONS of medicines containing FINASTERIDE, which is a specific inhibitor of type II 5a-reductase, an intracellular enzyme that metabolizes testosterone to convert it into a more potent androgen, 5a-dihydrotestosterone (DHT) that appears to be the main androgen responsible for the stimulation of prostate growth. Finasteride at a dose of 1 mg is indicated for the treatment of hair loss in men with androgenetic alopecia and at a dose of 5 mg it is indicated for the treatment and control of Benign Prostatic Hyperplasia.

This decision is based on safety information from the UK High Surveillance Agency (MHRA) and the European Medicines Agency (EMA) which inform healthcare professionals and patients of the following:

- Finasteride has been reported to cause mood disturbances, depression, suicidal behavior and suicidal ideation.

In this sense, health professionals are recommended to:

- After initiation of finasteride, observe patients for psychiatric problems. Advise patients to discontinue finasteride treatment if they develop mood disturbances, depression, and suicidal ideation.

- Instruct patients to inform their physician if they experience mood swings, depression and suicidal ideation while taking finasteride.

Patients and caregivers are advised to:

- If you experience mood swings, depression and suicidal thoughts, stop taking finasteride and see your doctor as soon as possible.

Finally, it is recalled that it is necessary and mandatory to report to the Peruvian System of Pharmacovigilance and Technovigilance, suspected adverse reactions that are observed due to the use of pharmaceutical products that are marketed in our country, to the email: pharmacovigilancia@digemid.gob.pe

Lima, March 26, 2018

1. The requirement of the technical file is enforceable as of January 9, 2018

2. Medicines and Healthcare Products Regulatory Agency – MHRA. Finasteride: rare reports of depression and suicidal thoughts. [Access date: June 27, 2017]. Published: May 24, 2017. Available at: https://www.gov.uk/drug-safety-update/finasteride-rare-reports-of-depression-and-suicidal-thoughts
3. European Medicines Agency – EMA. Periodic safety update report single assessments-Finasteride: CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00001392/201o08. [Access date: June 27, 2017]. Published: May 30, 2017. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Periodic_safety_update_single_assessment/2017/05/WC500228o84.pdf