

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

**Colombian National Institute for Food and Drug Surveillance
Information for Health Professionals, Patients and Caregivers
FINASTERIDE**

Bogotá, November 30, 2017—Based on the recommendation issued by the reference agencies (GOV.UK, EMA, FDA) regarding rare cases of depression and suicidal thoughts associated with finasteride use, the National Institute for Food and Drug Surveillance (INVIMA) informs health professionals, patients and caregivers:

- Finasteride is a drug whose mechanism of action is based on the selective competitive inhibition of the enzyme 5- α reductase type 2.
- Rare cases (1/1,000 to 1/10,000) of depression, suicidal thoughts and sexual dysfunction have been identified in the UK in men being treated with finasteride.
- Medications containing finasteride are authorized for the management of alopecia. Based on the abovementioned, INVIMA recommends taking the following measures, to minimize the risks associated with finasteride consumption:

MEASURES FOR HEALTH PROFESSIONALS

- Patients treated with finasteride should be warned about the possibility of developing depressive disorders, as well as sexual dysfunction, while receiving this medicine.
- Although the frequency of appearance of the abovementioned events is unknown, in case they occur, evaluate the risk-benefit balance of continuing treatment the medication.
- In case of serious side effects related to the use of this medicine, report to the National Pharmacovigilance Program through the INVIMA website [here](#).

If more information is available, INVIMA will issues updates accordingly.

MEASURES FOR THE COMMUNITY IN GENERAL

- If you are taking finasteride and develop symptoms associated with depression or sexual dysfunction, consult your doctor immediately.

- It is important to report adverse events associated with the active ingredient finasteride to the National Pharmacovigilance Program through the INVIMA [website](#):
 - Citizen Information Services
 - Complaints, Complaints and Claims
 - Complaints and Claims
 - File Procedure
 - Complaints and Claims

- Patients also report by registering through the reporting online platform, here. If/when new safety information becomes available, INVIMA will update the public according. Remember: do not self-medicate. Your health safety is important.

Reference: [Medicines and Healthcare products Regulatory Agency \(UK\): Finasteride: rare reports of depression and suicidal thoughts, May 24, 2017](#)