SAFETY ALERT

DRAP SAFTEY ALERT NO. 63

Safety Alert of Potential Risk of Suicidal Thoughts with Finasteride and Dutasteride-containing medicines

Date: 3rd of February, 2026

Target Audience.

- Provincial Health Departments/Provincial PV Centres;
- Manufacturers and importers of Finasteride and Dutasteride-containing medicines;
- Healthcare Professionals; and
- Patients.

Background.

The PRAC of the EMA, in its meeting of 5th -8th of May, 2025, concluded its review following referral by France. The PRAC reviewed the available data in relation to suicidal ideation and behaviours associated with the use of finasteride- and dutasteride-containing products. The data included the responses submitted by the MAHs in writing, data from clinical trials, spontaneous reporting and literature, non-clinical data, as well as interventions by third parties. Based on the evaluated cases of suicidal ideation or suicidal behaviours reported with oral finasteride, PRAC confirmed a causal association between oral finasteride and suicidal ideation. Therefore, suicidal ideation should be reflected as an undesirable effect in the product information of all medicinal products containing finasteride 1 mg or finasteride 5 mg for oral use, with a frequency 'not known'. PRAC noted that the product information of all medicinal products containing finasteride 1 mg or finasteride 5 mg for oral use already includes a warning on mood alterations, including suicidal ideation. PRAC also concluded that sexual dysfunction, a known adverse drug reaction of finasteride, may have a contributory role in suicidal ideation in some patients being treated with finasteride 1 mg for oral use and recommended that this to be reflected as a warning in the product information of these products.

The product information for finasteride 1 mg *will now also alert patients* about the need to seek medical advice if they experience problems with sexual function that have been reported to contribute to mood alterations and suicidal ideation in some patients. *A patient card* will be included in the 1 mg finasteride package to remind patients of these risks and to advise them about the appropriate course of action. Regarding finasteride-containing medicinal products for cutaneous use, PRAC did not identify sufficient evidence linking suicidal ideation to such products that would prompt an update of the existing warning on mood alterations. Thus, PRAC considered that the benefit-risk balance of medicinal products containing finasteride for cutaneous use remains favourable and recommended the maintenance of their marketing authorisations.

The PRAC confirmed that suicidal ideation (suicidal thoughts) is an adverse reaction of finasteride tablets, but concluded that the benefits of finasteride and dutasteride medicines continue to outweigh their risks for all approved uses. The frequency of the adverse reaction is unknown. Although a link between suicidal ideation and dutasteride was not established based on the reviewed data, dutasteride works in the same way as finasteride. Therefore, information about the mood changes seen with finasteride will also be added to dutasteride's product information as a precaution.

Action in Pakistan.

The case was previously discussed in the 2nd meeting of PRAEC-DRAP held on 7th March, 2023, as per the decision of the Health Sciences Authority (HSA) of Singapore and Health Canada. The PRAEC decided, as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022, that registration holders should update prescribing information/safety specification of Finasteride-containing drugs by strengthening the warning statements on the risks of suicidal ideation and self-injury, and to include information about patient screening for psychiatric risk factors before starting treatment.

The case was again discussed in the 6th meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) held on 31st of December, 2025 which decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022, that registration holders are required to include the risk of suicidal ideation (suicidal thoughts) in the Adverse Drug Reactions section, with a frequency of "unknown", for oral finasteride and dutasteride-containing medicines registered in Pakistan, in line with the decision of EMA-PRAC.

Therapeutic Good Affected.

Name: Finasteride (oral 1 mg tablet) is used to treat the early stages of androgenic alopecia in men aged 18 to 41 years. Finasteride (oral 5 mg tablet) and dutasteride (0.5 mg capsules) are used to treat men with benign prostatic hyperplasia (BPH).

Advice for Healthcare Professionals.

Healthcare professionals are informed that there may be a potential risk of mood alterations, including depressed mood, depression and, less frequently, suicidal ideation (suicidal thoughts), with a frequency of "unknown" has been reported in patients treated with Finasteride. Healthcare professionals are hereby advised to consider the potential risk of psychological adverse events when assessing the benefit-risk of finasteride for their patients. Most cases of suicidal ideation were reported in people using 1 mg finasteride to treat hair loss due to male hormones. Healthcare professionals should also advise their patients to consult their doctors at the earliest when such thoughts are developed.

Advice for patients.

Patients are advised to immediately consult their doctors if they experience mood alterations, including depression and, less frequently, suicidal ideation (suicidal thoughts) during their treatment with Finasteride and Dutasteride.

Guidelines for reporting Adverse Drug Reactions (ADRs).

Healthcare professionals and patients are requested to report any adverse drug reaction/ event with Finasteride and Dutasteride-containing medicines and/or any other medicines to the National Pharmacovigilance Centre (NPC), Drug Regulatory Authority of Pakistan (DRAP), through the Med Vigilance E-Reporting System (E-forms) available on the DRAP website. Similarly, adverse events and adverse drug reactions can also be reported through the VigiMobile App by scanning the following QR code, which can also be downloaded (add to home screen) in the mobile:

References.

- Minutes of the 6th meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC), DRAP.
- EMA-PRAC: Minutes for PRAC meeting on 05-08 May 2025.
- Minutes of the 2nd meeting of the Pharmacovigilance Risk Assessment Expert Committee.
- Health Canada: Summary Safety Review - Finasteride - Assessing the Potential Risks of Suicide, Suicidal Thoughts (Suicidal Ideation) and Self-injury

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