Medicines & Healthcare products Regulatory Agency

DRUG SAFETY UPDATE (DSU)

Finasteride and Dutasteride – updated safety warnings for psychiatric side effects and sexual dysfunction

Specialisms: *Dermatology, Dispensing GP practices, Emergency medicine, General practice, Pharmacy, Psychiatry, Renal medicine, Urology and nephrology*

Summary

The MHRA has reviewed the evidence[1] for finasteride and dutasteride and the risk of suicidal thoughts and behaviours and has recommended further measures to minimise this risk. The product information for finasteride and dutasteride containing medicines is being updated to provide more information on these side effects. The UK Finasteride patient cards, already introduced in 2024, highlight the risks of psychiatric and sexual side effects.

Advice for Healthcare Professionals:

- finasteride is associated with depression, suicidal ideation and sexual dysfunction which may persist after treatment is stopped
- inform patients of the risks at point of prescribing and advise patients to read the Finasteride patient cards and the patient leaflet for finasteride which are both supplied in the 1 mg and 5 mg packs
- the product information for finasteride 1 mg will be updated with a warning that sexual dysfunction may contribute to mood disorders, and that sexual dysfunction has also been reported without mood alterations
- when prescribing finasteride, review their medical record, ask patients if they have a history of depression or suicidal ideation and review patients regularly for psychiatric and/or sexual side effects
- patients prescribed finasteride 1 mg should stop taking the medicine if they develop suicidal thoughts or depression and contact their healthcare professional as soon as possible
- patients prescribed finasteride 5mg or dutasteride should consult their healthcare professional as soon as possible if they develop suicidal thoughts or depression
- dutasteride works in a similar way to finasteride – therefore, as a precaution, a warning will be added to the dutasteride product information that mood alterations have been reported with the same class of medicine (finasteride)

- patients prescribed finasteride or dutasteride should contact their healthcare professional if they experience sexual dysfunction
- report suspected adverse drug reactions associated with finasteride or dutasteride using the Yellow Card scheme

Advice for Healthcare Professionals to Provide to Patients:

- finasteride is associated with low mood, depression, suicidal thoughts and sexual dysfunction (decreased sex drive, erectile dysfunction and ejaculation disorders)
- before taking finasteride, read and keep the Finasteride patient cards and patient information leaflet within your pack and inform your doctor if you have any personal history of depression or suicidal thoughts
- if you have seriously harmed yourself or feel you are at risk of serious harm, contact emergency services on 999 immediately
- stop finasteride 1mg immediately if you develop depression or suicidal thoughts and contact your doctor as soon as possible
- if you are prescribed finasteride 5mg or dutasteride and you develop depression or suicidal thoughts, contact your doctor as soon as possible
- if prescribed finasteride or dutasteride and you experience decreased sex drive, difficulty having an erection or ejaculation problems you should contact your doctor for medical advice

Background

Finasteride is a 5 alpha-reductase-inhibitor. The 1mg dose is indicated in men for the treatment of male pattern hair loss (androgenetic alopecia). The 5mg dose is indicated for the treatment and control of benign prostatic hyperplasia in adults.

Dutasteride is also a 5-alpha-reductase-inhibitor. It is indicated for the treatment of benign prostatic hyperplasia (0.5 milligram daily dose) and reduction in the risk of acute urinary retention. It is available as dutasteride alone or in combination with tamsulosin.

The MHRA issued a previous Drug Safety Update in April 2024 regarding finasteride, providing a reminder of the risks of psychiatric and sexual side effects with finasteride and introducing the patient cards.

The MHRA reviewed the scientific literature included in the European referral[1], Yellow Card reports and the actions taken by other international regulators. Evidence was

considered by the Pharmacovigilance Expert Advisory Group (PEAG) of the Commission on Human Medicines (CHM) and the Commission on Human Medicines (CHM). The PEAG and CHM advice included updating the product information of finasteride 1mg and retaining the UK finasteride patient cards for the 1mg and 5mg finasteride products. The data from Yellow Card reports were mainly from patients treated with 1mg finasteride for androgenetic alopecia, and the literature data showed mixed outcomes. The data for dutasteride was very limited, therefore, PEAG and CHM recommended updating the dutasteride product information as a precaution.

Product Information Update

The SmPC and PIL for finasteride 1mg are being updated with a warning that sexual dysfunction may contribute to mood disorders, which has been reported in some patients, and sexual dysfunction has also been reported without mood alterations. For dutasteride, a warning will be added to the SmPC and PIL that depressed mood, depression or suicidal ideation has been reported in patients receiving another medicine from the same class (finasteride).

Usage

Prescribing data suggests more than 400,000 prescriptions per month are issued for finasteride 5mg and dutasteride containing medicines[2]. As finasteride 1mg is not prescribed on the NHS and is only available by private prescription, accurate prescription numbers are not available.

Yellow Card data

Yellow Card data since 1994 to 31 May 2025 includes 170 reports of suicidal ideation and related terms for finasteride (1mg and 5mg) and 5 reports for dutasteride 0.5mg. There were 19 fatal reports of suicide for finasteride and no fatal reports of suicide for dutasteride.

Yellow card reports have been reported to the MHRA by healthcare professionals, members of the public and pharmaceutical companies. The suspected adverse reactions that have been reported do not necessarily mean that the medicine has caused the reaction. Many factors should be considered with careful analysis to assess these data.

Reporting advice

Healthcare professionals, patients, and caregivers are asked to submit reports using the Yellow Card scheme electronically using:

- the Yellow Card website.
- the Yellow Card app; download from the Apple App Store or Google Play Store

- some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank, and Ulysses)

When reporting suspected adverse drug reactions, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, and treatment dates.

Additional information

You can sign up to receive email notifications for Drug Safety Updates.

You can sign up to receive our monthly roundup of safety communications.

For any enquiries, please contact info@mhra.gov.uk

References

1. Finasteride- and dutasteride-containing medicinal products - referral | European Medicines Agency (EMA)
2. Home | OpenPrescribing

Stakeholder engagement:

- Royal College of General Practitioners
- British Association of Urological Surgeons
- NHS England Patient Safety and Devolved Administrations

Article citation: MHRA Drug Safety Update May 2026 1