20 June 2025
EMA/202053/2025

# Measures to minimise risk of suicidal thoughts with finasteride and dutasteride medicines

## Suicidal thoughts confirmed as side effect of finasteride tablets; no direct link found for dutasteride

On 19 June 2025, the CMDh[1] endorsed measures recommended by EMA's safety committee, PRAC, to minimise the risk of suicidal ideation (suicidal thoughts) with finasteride and dutasteride medicines. Suicidal ideation was confirmed as a side effect of finasteride 1 and 5 mg tablets by the PRAC, following an EU-wide review of available data on these medicines. The frequency of the side effect is unknown, meaning that it is not possible to estimate it from available data.

Most cases of suicidal ideation were reported in people using 1 mg finasteride tablets, which are used to treat androgenetic alopecia (hair loss due to male hormones). A warning about mood changes, including depression, depressed mood and suicidal ideation, is already included in the product information for finasteride medicines. Patients who experience mood changes should seek medical advice and, if taking finasteride 1 mg, should also stop treatment.

The product information for finasteride 1 mg tablets will now also alert patients about the need to seek medical advice if they experience problems with sexual function (such as decreased sex drive or erectile dysfunction), which are known side effects of the medicine and may contribute to mood changes.

A patient card will be included in the packages of 1 mg finasteride tablets to remind patients of these risks and to advise them about the appropriate course of action.

These recommendations follow a review of the risks of suicidal thoughts and behaviours with finasteride and dutasteride medicines. The PRAC agreed that suicidal ideation should be included as a side effect of finasteride tablets but concluded that the benefits of finasteride and dutasteride medicines continue to outweigh their risks for all approved uses.

Finasteride 1 mg tablets and finasteride skin spray are used to treat early androgenetic alopecia (hair loss due to male hormones), while finasteride 5 mg tablets and dutasteride 0.5 mg capsules are used to treat benign prostatic hyperplasia (enlarged prostate that can cause problems with urine flow).

[1] The CMDh is a body representing EU Member States as well as Iceland, Liechtenstein and Norway. It is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

**Dutasteride tablets and finasteride skin sprays**

Although it was not possible to establish a link between suicidal ideation and dutasteride based on the reviewed data, dutasteride works in the same way as finasteride and therefore information about the mood changes seen with finasteride will also be added to dutasteride's product information as a precaution.

The review found no evidence linking suicidal ideation to finasteride skin sprays and no new information is being included in the product information for these sprays.

**Data assessed by the PRAC**

In reaching its conclusion, the PRAC assessed available information on the effectiveness and safety of finasteride and dutasteride medicines, including data from clinical trials, EudraVigilance (the European database of reported suspected side effects), literature case reports and studies in the scientific literature.

The review identified 325 relevant cases of suicidal ideation in EudraVigilance, 313 reported for finasteride and 13 for dutasteride (with 1 case reported for both). These cases were considered either probably or possibly related to treatment, and most cases concerned patients treated for alopecia. These numbers were considered in the context of an estimated exposure of around 270 million patient years for finasteride and around 82 million patient years for dutasteride (1 patient year is the equivalent of one patient taking the medicine for one year).

The Committee also considered information received during the review from patients or their relatives, healthcare professionals, academics, and patient and consumer organisations, who shared their experiences with finasteride treatment and/or provided additional data on finasteride use.

**Information for patients**

- Finasteride tablets can cause depressed mood, depression or suicidal thoughts. If you are taking finasteride 1 mg tablets for hair loss and you experience any mood changes, stop taking finasteride and contact your doctor for further medical advice as soon as possible.
- In some patients taking 1 mg finasteride tablets, problems with sexual function (such as less desire to have sex, difficulty having an erection and problems with ejaculation) may contribute to mood changes, including suicidal thoughts. If you experience problems with sexual function, contact your doctor for further medical advice.
- If you are taking 1 mg finasteride tablets, you will receive a patient card in the package informing you about these risks and what action to take if you experience symptoms of mood change or problems with sexual function.
- Suicidal thoughts are a side effect of finasteride tablets used to treat hair loss (1 mg) or benign prostatic hyperplasia (5 mg). Most cases were reported in people using the medicine for hair loss.
- Based on the available evidence, no link could be found between suicidal thoughts and the use of either finasteride as a skin spray (to treat hair loss) or dutasteride capsules (to treat benign prostatic hyperplasia). Because dutasteride works in the same way as finasteride, as a precaution its product information will include information about the possible risk of mood changes, including suicidal thoughts.
- If you are taking dutasteride, you should seek medical advice if you experience depressed mood, depression or suicidal thoughts.

- If you have further questions about your treatment, please contact your healthcare professional.

**Information for healthcare professionals**

- Advise patients using 1 mg oral finasteride for androgenetic alopecia to stop treatment and seek medical advice if they experience depressed mood, depression or suicidal ideation.
- Some patients using 1 mg oral finasteride have reported sexual dysfunction, which may contribute to mood alterations, including suicidal ideation. Inform patients to seek medical advice if they experience signs of sexual dysfunction and consider discontinuing treatment.
- A patient card will be included in the packages of 1 mg finasteride tablets to inform patients being treated for androgenetic alopecia about these possible side effects and the appropriate course of action.
- The Agency's recommendations are based on an EU-wide review of available data on medicines containing finasteride (1 and 5 mg tablets and cutaneous spray solutions) and dutasteride (0.5 mg capsules). The review concluded that the level of evidence of the risks differed according to the indications, active substances and formulations.
- The review found insufficient evidence to establish a causal association between dutasteride and the risk of suicidal ideation. As a precautionary measure, based on a possible class effect of 5-alpha reductase inhibitors (5-ARIs), the product information for dutasteride will be updated to include information about the potential risk of suicidal ideation.
- A direct healthcare professional communication (DHPC) will be sent to relevant healthcare professionals in due course and published on a dedicated page on the EMA website.

---

**More about the medicines**

Medicines containing finasteride 1 mg tablets or sprays to be applied to the skin are authorised in various EU Member States to prevent hair loss and stimulate hair growth in men aged 18 to 41 years with early-stage androgenetic alopecia (hair loss due to male hormones).

Medicines containing finasteride 5 mg tablets and dutasteride (0.5 mg capsules) are authorised to treat symptoms of benign prostatic hyperplasia (BPH), a condition in which the prostate is enlarged, which may cause problems with the flow of urine.

In the EU, finasteride- and dutasteride-containing medicines are available under various trade names such as Adadut, Androfin, Andropecia, Avodart, Capila, Combodart, Duodart, Dupro, Duster, Dutaglandin, Dutalosin, Dutascar, Finahair, Finapil, Finapuren, Finaristo, Finpros, Finural, Fynzur, Gefina, Propecia, Proscar, Prosmin, Prosterid, Tadusta and others.

Finasteride and dutasteride work by preventing an enzyme called 5-alpha reductase (5-AR) from changing testosterone (a male hormone) into 5-alpha-dihydrotestosterone (DHT), which is involved in hair loss and enlargement of the prostate. By keeping 5-AR from working, finasteride and dutasteride decrease levels of DHT. This slows down hair loss and stimulates hair growth and decreases the size of the prostate.

**More about the procedure**

The review of medicines containing finasteride and dutasteride was initiated at the request of the French medicines agency, under Article 31 of Directive 2001/83/EC.

The review was carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which issued a set of recommendations. The PRAC recommendations were forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which has adopted its position. As the CMDh position was adopted by majority vote, it will now be sent to the European Commission, which will issue an EU-wide legally binding decision.