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

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15/07/2025 | Circular Number P03/2025

### **Information on finasteride and dutasteride**

- Medicines containing finasteride 1mg tablets or sprays to be applied to the skin are authorised 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 5mg tablets and dutasteride 0.5mg 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, Proscin, 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.



The following products are authorised via national procedure:

Active Ingredients	Product Name	Pharmaceutical Form	Classification	Authorisation Number	MAH/license holder
Finasteride 1 milligram(s)	Propecia	Film-coated tablets	POM	MA031/02001	N.V. Organon
Finasteride 1 milligram(s)	Finasteride	Film-coated tablets	POM	MA807/06901	Aurobindo Pharma (Malta) Limited
Finasteride 1 milligram(s)	Finasteride Biorga	Film-coated tablets	POM	MA1106/00301	Laboratoires Bailleul S.A.
Finasteride 1 milligram(s)	Propecia	Film-coated tablets	POM	PI908/25301A	NeoFarma Pharmaceuticals Limited
Finasteride 1 milligram(s)	Finasteride Stada	Film-coated tablets	POM	AA912/01401	Pharma MT
Finasteride 5 milligram(s)	Finasteride	Film-coated tablets	POM	PI770/13501A	JV Healthcare Limited
Finasteride 5 milligram(s)	Finasteride Aurobindo	Film-coated tablets	POM	MA807/10001	Aurobindo Pharma (Malta) Limited
Finasteride 5 milligram(s)	Finasteride Aurobindo	Film-coated tablets	POM	PI908/11501A	NeoFarma Pharmaceuticals Limited
Finasteride 5 milligram(s)	Finasteride Aurobindo	Film-coated tablets	POM	PI1438/08101A	NM Pharma Limited
Finasteride 5 milligram(s)	Finasteride Ascend	Film-coated tablets	POM	MA1431/00401	Ascend GmbH c/o Pollux Business Center GmbH
Finasteride 5 milligram(s)	Finasteride Zentiva	Film-coated tablets	POM	AA1173/08002	Mint Health Ltd
Finasteride 5 milligram(s)	Finasteride 5mg	Film-coated tablets	POM	AA565/59101	Central Procurement & Supplies Unit
Finasteride 5 milligram(s)	Finasteride 5mg	Tablets	POM	AA565/59102	Central Procurement & Supplies Unit
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Combodart	Hard Capsule	POM	MA192/02601	Glaxo SmithKline Ireland Limited
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Combodart	Hard Capsule	POM	PI908/08101A	NeoFarma Pharmaceuticals Limited
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Dyoster	Hard Capsule	POM	MA214/01201	Rafarm S.A



Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Dutamin	Hard Capsule	POM	MA255/03401	Galenicum Health, S.L
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Dutasteride/ Tamsulosin Sandoz	Hard Capsule	POM	MA685/03601	Sandoz Pharmaceuticals d.d
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Dutasteride/ Tamsulosin Hydrochloride	Hard Capsule	POM	MA1269/09001	Accord Healthcare Ireland Ltd
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Dutasteride/ Tamsulosin Biogran	Hard Capsule	POM	MA1218/00201	Biogaran
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Dutasteride / Tamsulosin Genepharm	Hard Capsule	POM	MA089/01001	Genepharm S.A.
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Prostatyl	Hard Capsule	POM	MA1291/00101	Lavipharm S.A
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Dutasteride/ Tamsulosin Q Pharma	Hard Capsule	POM	MA1319/00101	Laboratorios Q Pharma, S.L
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Dutasteride/ Tamsulosin Galenicum Health	Hard Capsule	POM	MA255/04401	Galenicum Health, S.L.
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Dutasteride/ Tamsulosin Hydrochloride	Hard Capsule	POM	PI1330/00701A	Azure Pharmaceuticals Ltd
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	AMDUT Combo	Hard Capsule	POM	AA729/25601	Cherubino Limited
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Atucare	Hard Capsule	POM	MA1006/01101	Heaton k.s.
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Combodart	Hard Capsule	POM	PI1438/05701A	NM Pharma Limited
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Duplotrip	Hard Capsule	POM	MA1519/00101	GP-Pharm, S.A.



Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Dutasteride/ Tamsulosin Olpha	Hard Capsule	POM	MA1542/00401	Olpha AS
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Combodart	Hard Capsule	POM	PI908/08101B	NeoFarma Pharmaceuticals Limited
Dutasteride 0.5 milligram(s)   Tamsulosin 0.4 milligram(s)	Combodart	Hard Capsule	POM	PI770/22901A	JV Healthcare Limited
Dutasteride 0.5 milligram(s)	Avodart	Soft Capsules	POM	MA192/02701	Glaxo SmithKline Ireland Limited
Dutasteride 0.5 milligram(s)	Dutasteride Galenicum	Soft Capsules	POM	MA255/00801	Galenicum Health, S.L.
Dutasteride 0.5 milligram(s)	Dutasteride Doc Generici	Soft Capsules	POM	MA1066/00201	Doc Generici srl
Dutasteride 0.5 milligram(s)	Dutasteride	Soft Capsules	POM	MA1269/03801	Accord Healthcare Ireland Ltd
Dutasteride 0.5 milligram(s)	Dutalan	Soft Capsules	POM	MA993/00201	G.L. Pharma GmbH
Dutasteride 0.5 milligram(s)	DutaPro	Soft Capsules	POM	MA1485/00401	Viartis Limited
Dutasteride 0.5 milligram(s)	Dutasteride Galenicum Health	Soft Capsules	POM	MA255/02601	Galenicum Health, S.L.
Dutasteride 0.5 milligram(s)	Dutasteride Mylan	Soft Capsules	POM	MA1465/00801	Mylan Pharmaceuticals Limited
Dutasteride 0.5 milligram(s)	Avodart	Soft Capsules	POM	PI908/15802A	NeoFarma Pharmaceuticals Limited
Dutasteride 0.5 milligram(s)	Dutasteride Olpha	Soft Capsules	POM	MA1542/00201	Olpha AS

### Information from the EMA about the safety concern

- The Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) endorsed measures recommended by EMA’s safety committee, the Pharmacovigilance Risk Assessment Committee (PRAC), to minimise the risk of suicidal ideation and suicidal thoughts with finasteride and dutasteride medicines. Suicidal



ideation was confirmed as a side effect of finasteride 1mg and 5mg 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 1mg 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, along with advice to stop treatment and seek medical advice.
- The product information for finasteride 1mg 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 1mg finasteride tablets to remind patients of these risks and to advise them about the appropriate course of action.
- The 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.
- No link between suicidal ideation and dutasteride was established. 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.



- 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.

### **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 PRAC, which issued a set of recommendations. The PRAC recommendations were forwarded to the CMDh.
- On 19 June 2025, the CMDh endorsed measures recommended by the PRAC, to minimise the risk of suicidal ideation (suicidal thoughts) with finasteride and dutasteride medicines.
- 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



## Information for Healthcare Professionals

- Advise patients using 1mg oral finasteride for androgenetic alopecia to stop treatment and seek medical advice if they experience depressed mood, depression or suicidal ideation.
- Some patients using 1mg 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 1mg 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 (1mg and 5mg tablets and cutaneous spray solutions) and dutasteride (0.5mg 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.



## **Information for Patients**

- Finasteride tablets can cause depressed mood, depression or suicidal thoughts. If you are taking finasteride 1mg 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 1mg 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 1mg 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 (1mg) or benign prostatic hyperplasia (5mg). 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 3 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.



## **Reporting Adverse Drug Reactions**

Healthcare professionals and patients are encouraged to maintain vigilance with finasteride 1mg, finasteride 5mg and dutasteride 0.5mg. Suspected adverse drug reactions (side effects) may be reported using the Medicines Authority Form and sending it to: Sir Temi Zammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 **or** online to <http://www.medicinesauthority.gov.mt/adrportal> or to the marketing authorisation holder or their local representatives.

## **Post-Licensing Directorate**

### **Medicines Authority**

*Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.*



## Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health.

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this form (address side up), stapling the ends and then posting (no stamp required).

### Feedback:

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