PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Direct Healthcare Professional Communication

12th September 2025

Finasteride, dutasteride – New measures to minimise the risk of suicidal ideation

Dear Healthcare professional,

Marketing authorisation holders of finasteride and dutasteride (refer to page 4 of this letter for company contact points), in agreement with the European Medicines Agency and the Health Products Regulatory Authority (HPRA) would like to inform you of the following:

Summary

- **Suicidal ideation is an adverse reaction of oral finasteride-containing products, mainly reported in patients treated for androgenetic alopecia.**
- **Advise patients treated with oral finasteride for androgenetic alopecia to stop treatment and seek medical advice if they experience depressed mood, depression or suicidal ideation.**
- **Sexual dysfunction that may contribute to mood alterations, including suicidal ideation, has been reported in some patients treated for androgenetic alopecia. Inform patients to seek medical advice in case of experiencing sexual dysfunction and consider discontinuation of treatment.**
- **A patient card will be available in the package of medicinal products containing finasteride 1 mg to highlight the risks of depressed mood, depression, suicidal ideation and sexual dysfunction reported with finasteride.**
- **Despite the insufficient evidence to establish a direct association of suicidal ideation with dutasteride, and based on the common mechanism of action for medicinal products of the class of 5-alpha reductase inhibitors, patients treated with dutasteride should be recommended to seek prompt medical advice if symptoms of mood alterations occur.**

Background on the safety concern

Finasteride and dutasteride are 5-alpha-reductase inhibitors (5-ARIs). Finasteride is an inhibitor of the enzyme 5-alpha-reductase types 1 and 2 with a greater affinity for type 2. Dutasteride targets both isoforms of this enzyme.

Lower dose oral formulations of finasteride (1 mg) are indicated for the treatment of male pattern hair loss in an early stage (androgenetic alopecia). A cutaneous spray solution of finasteride 2.275 mg/mL (topical) is authorised in the same indication. Higher dose oral formulations of finasteride (5 mg) including combinations with either tadalafil or tamsulosin are indicated for the symptomatic treatment of benign prostatic hyperplasia and for the prevention of urologic events. Dutasteride. available only as oral formulations, including combinations with tamsulosin are indicated for the management of symptomatic benign prostatic hyperplasia. For finasteride- and dutasteride-containing medicinal products, some psychiatric disorders are known risks and are already reflected in the product information.

Following an EU-wide review by the European Medicines Agency (EMA) of the available data regarding suicidal ideation and behaviours reported with 5-ARIs, it was concluded that the level of evidence for these events differs according to the respective indications, active substances and formulations.

Within the review, 325 relevant cases of suicidal ideation have been identified in EudraVigilance, the European database of suspected adverse drug reaction reports. 313 cases were reported for finasteride and 13 for dutasteride (1 case reported the use of both finasteride and dutasteride). Most of the cases were reported for patients treated for alopecia, while a 10-times lower number of cases were reported for patients treated for benign prostate hyperplasia. These numbers should be considered in the context of the estimated exposure for finasteride of approximately 270 million patient years, and for dutasteride, approximately 82 million patient years.

Finasteride 1 mg (androgenetic alopecia)

Following the review of the available data, the EMA confirms that suicidal ideation is an adverse drug reaction with the frequency not known, meaning that it cannot be estimated from the available data. The current product information of these formulations already contains a warning on mood alterations including suicidal ideation, together with a recommendation to stop treatment and seek prompt medical advice if these symptoms occur. In addition, the review identified cases of suicidal ideation in which sexual dysfunction (a known adverse drug reaction of finasteride) contributed to the development of mood alterations, including suicidal ideation. Warnings and precautions for use will be updated to advise patients to consult their doctor if they experience sexual dysfunction, and discontinuation of the treatment should be considered.

A patient card will be included in the package to inform about the risks of mood alterations, including suicidal ideation, and of sexual dysfunction and to advise on the appropriate actions to be taken.

Finasteride 5 mg (benign prostatic hyperplasia) including combinations with tadalafil or tamsulosin

The review also confirmed that suicidal ideation is an adverse drug reaction with the frequency not known (cannot be estimated from the available data). The current product information of these formulations already contains a warning on mood alterations, including suicidal ideation, together with the recommendation to seek prompt medical advice if these symptoms occur.

Topical finasteride (androgenetic alopecia)

The product information already contains information about the risks of mood alterations associated with the use of oral finasteride**.** There is currently insufficient evidence to support a causal association between topical finasteride and the risk of suicidal ideation. Therefore, no product information update is introduced.

Dutasteride 0.5 mg (benign prostatic hyperplasia) including combinations with tamsulosin

Although there is insufficient evidence to establish a risk of suicidal ideation with dutasteride, as a precautionary measure, and based on the evidence for another oral 5-ARI, warnings and precautions for use will be updated to inform about the potential risk of suicidal ideation, with a recommendation that patients should seek prompt medical advice if symptoms of mood alterations occur.

Call for reporting

Please report any suspected adverse reactions associated with the use of finasteride- and dutasteride-containing products in accordance with the national requirements via the national spontaneous reporting system, to HPRA Pharmacovigilance, website: www.hpra.ie.

Suspected adverse reactions should also be reported to the relevant Marketing Authorisation Holders (see contact details below).

Company contact points

If you have any questions, or if you require any further information, please contact the medical information service of the relevant Marketing Authorisation Holder.

Product Name (s)	Marketing Authorisation Holder	Contact point details
Finasteride Accord Healthcare Ireland (5 mg) Dutasteride/Tamsulosin Hydrochloride Accord Healthcare Ireland (0.5 mg, 0.4 mg)	Accord Healthcare Ireland Ltd	Accord Healthcare Ireland Ltd Euro House, Euro Business Park, Little Island, Cork, T45 K857, Ireland medinfo@accord-healthcare.com +44 (0) 1271 385 257
Fintrid 5mg(finasteride)	Aurobindo Pharma (Malta) Limited	APL Swift Services (Malta) Ltd. HF26, Hal Far Industrial Estate, Birzebbugia BBG 3000 Malta Pharmacovigilance.UK@aurobindo.com MEDINFO@aurobindo.com + 44 (0)208 845 8811
Finasteride Careforsons Ireland 1 mg(finasteride)	Careforsons Ireland Limited	Callisto Pharma Group 107 Regus Block 1, Blanchardstown Corporate Park, Dublin, D15 AKK1Office: +44 (0) 1332 812934 Head of PV: +44 (0) 7719 958241 pv@callistopharmagroup.com
Avodart (finasteride 0.5mg) Combodart (dutasteride 0.5mg)	Glaxosmithkline (Ireland) Limited	GlaxoSmithKline (Ireland) Limited ,12 Riverwalk, Citywest Business Campus, Dublin 24 Ireland GSK Medical Information 1800 244 255
Dutasteride Krka (dutasteride 0.5mg)	Krka, D.D., Novo Mesto	KRKA PHARMA DUBLIN LIMITED 1st Floor Unit H Citywest Shopping Centre Fortunes Walk, Saggart, DUBLIN, Ireland D24 TYT9 pharmacovigilance.ie@krka.biz +353 1 413 3710
Dutasteride/Tamsulosin Hydrochloride Mylan	Mcdermott Laboratories Ltd	Viatris, Newenham Court, Malahide Road, Northern Cross, Dublin D17 XC99, Ireland. info.ie@viatris.com +353 (0)1 8711600
Proscar (finasteride 5mg)	Organon Pharma (Ireland) Limited	Organon Pharma (Ireland) Limited, North Dock Dublin D01V4A3 Email: pv.ireland@organon.com Phone number: +353 1582 8260
Dutasteride Rowa Dutasteride/Tamsulosin Rowa	Rowa Pharmaceuticals Limited	Rowa Pharmaceuticals Ltd.Newtown, Bantry, Co. Cork Tel +353 02750077 Email: pv@rowa-pharma.ie
Dutasteride Teva	Teva Pharma B.V.	Teva Pharmaceuticals Ireland, Digital Office Centre Swords, Suite 101-103, Balheary Rd, Balheary Demesne, Swords, Co. Dublin Email: UK.Safety@tevauk.com www.tevauk.com
Dutasteride/Tamsulosin hydrochloride Pinewood 0.5 mg/0.4 mg hard capsules	Pinewood	Pinewood Healthcare, Ballymacarbry, Clonmel, Co. Tipperary, Ireland. email: drug.safety@pinewood.ie. Tel +353526186000

Yours faithfully,


Electronically signed by: Carola Rosseland
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Carola Rosseland, PhD

Executive Director, Medical Affairs, Northwest Europe

Organon Pharma (Ireland) Limited

Signed on behalf of the Marketing Authorisation Holders listed in the table above.