

Zentiva Pharma UK LTD
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Andrews House,
College Road,
Guildford,
GU1 4QB, UK

17th August 2026

Dear Healthcare professional,

Finasteride and dutasteride - Updated safety warnings for psychiatric side effects and sexual dysfunction

Medicines UK, on behalf of the following Marketing Authorisation Holders (MAHs) for finasteride and dutasteride containing medicines, is distributing this DHPC letter in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) to all Healthcare Professionals that prescribe or dispense these medicines to inform you of the following:

With regards to GPs and pharmacists, in line with the MHRA agreed distribution plan for this letter, this has been issued to one named GP or pharmacist within the practice/pharmacy. **Please ensure that this important information is disseminated to all GPs/HCPs/Pharmacists** in the practice/pharmacy who are likely to be involved in treating or dispensing to patients with finasteride or dutasteride.

Summary of the safety concern:

- **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. Sexual dysfunction may also occur without mood alterations. Inform patients to seek medical advice in case of experiencing sexual dysfunction and consider discontinuation of treatment.**
- **A Patient Alert Card is available in the package of medicinal products containing finasteride 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, 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 (androgenetic alopecia). Higher dose oral formulations of finasteride (5 mg) are indicated for the symptomatic treatment of benign prostatic hyperplasia and for the reduction of urologic events. Dutasteride is available as an oral formulation, including in combination with tamsulosin, and is indicated for the management of symptomatic benign prostatic hyperplasia. For finasteride and dutasteride containing medicinal products, some psychiatric side effects are already reflected in the product information.

Following a review by the MHRA 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, 170 reports of suicidal ideation have been identified in MHRA Yellow Card database of suspected adverse drug reactions and 5 reports for dutasteride up to 31 May 2025. Most of the cases were reported for patients treated for alopecia, although not all reports contain the dose or indication. Prescribing data suggests more than 400,000 prescriptions per month are issued for finasteride 5mg and dutasteride containing medicines. As finasteride 1mg is not prescribed on the NHS and is only available by private prescription, accurate prescription numbers are not available.

Finasteride 1 mg (androgenetic alopecia)

Following the review of the available data, the MHRA 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 and sexual dysfunction (a known adverse drug reaction of finasteride) which may have 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 Alert Card is 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)

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.

A Patient Alert Card is 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.

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 (finasteride), 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 continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the [Yellow Card website](#)
- the free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#)
- some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report suspected adverse drug reactions to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates and product brand name. By reporting side effects, you can help provide more information on the safety of this medicine.

Company contacts: Reporting of adverse reactions can also be made to the relevant company using the details provided in the table below. If you require further information about finasteride or dutasteride or have any questions, please contact the relevant MAH using the contact details provided.

The SmPC, Patient Information Leaflet and Patient Alert Card are also available at www.medicines.org.uk/emc or at the website locations cited in the table below or by email on request.

Yours sincerely,

RRP

Robert Russell-Pavier
Policy and Economics Director
Medicines UK
robert.russellpavier@medicinesuk.com

Table of Marketing Authorisation Holders and contact points:

MA Holder	Product name and strength	Contact email	SmPC/Risk Materials/ Patient leaflet location	Med Info contact
Accord Healthcare Ltd.	Finasteride 1 mg Film-coated Tablets	medinfo@accord-healthcare.com	https://www.accord-healthcare-products.co.uk/products/f/finasteride-tablets#variant-finasteride-1mg-film-coated-tablets	+44 (0)1271 385257
	Finasteride 5 mg Film-coated Tablets		https://www.accord-healthcare-products.co.uk/products/f/finasteride-tablets#variant-finasteride-5mg-film-coated-tablets	
	Dutasteride 0.5 mg soft capsules		https://www.accord-healthcare-products.co.uk/products/d/dutasteride-capsules#variant-dutasteride-0-5-mg-soft-capsules	
	Dutasteride/Tamsulosin 0.5mg/0.4mg Hard Capsules		https://www.accord-healthcare-products.co.uk/products/d/dutasteridetamsulosin-capsules#variant-dutasteridetamsulosin-hydrochloride-0-5mg0-4mg-hard-capsules	
Amarox Limited	Finasteride 1 mg film-coated tablets	safety@amaroxpharma.com	https://www.medicines.org.uk/emc/company/4214	+44(0)20397 20005
	Finasteride 5 mg film-coated tablets			
Ascend Laboratories (UK) Ltd.	Finasteride 5 mg film-coated tablets	amitkumar@alke.com	https://ascend-labs.co.uk	medinfo@ascend-labs.co.uk 0800 047 0073
Avianta Pharma Limited	Finasteride 1 mg Film-coated tablets	pv@northumbriapharma.com	Avianta Pharma Healthcare Professionals	ukmedinfo@aviantapharma.com
Bristol Laboratories Limited	Finasteride 1 mg film-coated tablets	info@bristol-labs.co.uk	https://bristol-labs.co.uk/	+44 (0) 1442 200 922
	Finasteride 5 mg film-coated tablets			info@bristol-labs.co.uk
Careforsons Limited	Finasteride 1mg film-coated tablets	hello@sons.co.uk	hello@sons.co.uk pv@callistopharmagroup.com	hello@sons.co.uk pv@callistopharmagroup.com

Cipla (EU) Limited	Finasteride 5 mg Film coated Tablets	Drugsafety@cipla.com	https://www.medicines.org.uk/emc/product/9958/smpc#greff	0800 0472144
Crescent Pharma Limited	Finasteride 5mg Film-coated tablets Dutasteride capsules 0.5mg	safety@crescentpharma.com medinfo@crescentpharma.com	https://www.crescentpharma.com SmPC/PIL - medinfo@crescentpharma.com	+44 (0)1217 901596
Dr. Reddy's Laboratories (UK) Ltd	Finasteride 5mg Tablets	drreddysgb@eu.propharmagroup.com	https://www.medicines.org.uk/emc/product/3493/rmms	+ 44 (0) 1748 828873
Ennogen IP Ltd	Dutasteride 0.5 mg soft capsules	RegulatoryAffairs@ennogen.com	https://www.medicines.org.uk/emc/	medicalinformation@ennogen.com
Generics (UK) Ltd T/A Mylan : UK	Finasteride 1mg Film-Coated Tablets Dutasteride/Tamsulosin hydrochloride 0.5 mg/0.4 mg hard capsule	Pv.uk@viatris.com	https://www.medicines.org.uk/emc/	Info.uk@viatris.com
Generics (UK) Ltd T/A Viatris : UK	Finasteride 5mg Film-Coated Tablets	Pv.uk@viatris.com	https://www.medicines.org.uk/emc/	Info.uk@viatris.com
Glaxosmithkline UK Limited	Avodart 0.5 mg soft capsules Combodart 0.5 mg / 0.4 mg hard capsules	uksafety@gsk.com	Home - electronic medicines compendium (emc): Combodart, Avodart	ukmedinfo@gsk.com 0800 221 441
Glenmark Pharmaceuticals Europe Ltd	Dutasteride/Tamsulosin hydrochloride Glenmark 0.5mg/0.4mg hard capsules	Medical_Information@glenmarkpharma.com	https://www.medicines.org.uk/emc/product/11336/smpc	Medical_Information@glenmarkpharma.com
LABORATORIOS LICONSA, S.A.	Dutasteride 0.5 mg soft capsules	Pharmacovigilance@chemogroup.com	Pharmacovigilance@chemogroup.com	Pharmacovigilance@chemogroup.com
LABORATORIOS LEON FARMA, S.A.	Dutasteride/Tamsulosin hydrochloride 0.5 mg/0.4 mg hard capsules	Pharmacovigilance@chemogroup.com	Pharmacovigilance@chemogroup.com	Pharmacovigilance@chemogroup.com
Milpharm Limited	Finasteride 1 mg film-coated tablets Finasteride 5 mg film-coated tablets Dutasteride 0.5 mg Soft capsules Dutasteride/Tamsulosin hydrochloride 0.5	medinfo@aurobindo.com	https://www.medicines.org.uk/emc/product/7068/smpc https://www.medicines.org.uk/emc/product/547/smpc https://www.medicines.org.uk/emc/product/9277/smpc https://www.medicines.org.uk/emc/product/12674/smpc	+44 (0) 208 845 8811

	mg / 0.4 mg hard capsules			
Northumbria Pharma Limited	Finasteride 1 mg Film-coated tablets	pv@northumbriapharma.com	MHRA Products Search results	pv@northumbriapharma.com
Organon Pharma (UK) Limited	PROPECIA 1mg Film-Coated Tablets PROSCAR 5 mg film-coated tablets	medicalinformationuk@organon.com	https://www.medicines.org.uk/emc/	+44 (0)208 159 3593 medicalinformationuk@organon.com
Relonchem Limited	Finasteride 1mg Tablets Finasteride 5mg Tablets	stephanie.kirby@bells-healthcare.com	https://relonchem.com/products/finasteride-1mg-tablets-x-84 https://relonchem.com/products/finasteride-5mg-tablets-x-28	VDedhia@ignat-services.com
Rudipharm Limited	Finasteride 1mg Tablets Finasteride 5mg Tablets	info@rudipharm.co.uk	Available on website	gms@rudipharm.co.uk
Strandhaven Limited t/a Somex Pharma	Finasteride 1mg Film Coated Tablets Finasteride 5mg Film Coated Tablets	pharmacovigilance@somexpharma.com	www.somexpharma.co.uk	akhtar@somexpharma.com 020 8590 9399
Strides Pharma UK Ltd	Dutasteride Strides 0,5 mg Capsule, Soft	Eu.ra@strides.com sadiq.basha@stridespharma.co.uk	https://www.medicines.org.uk/emc/	drugsafety@strides.com
Thornton and Ross Ltd.	Dutasteride/Tamsulosin hydrochloride 0.5 mg/0.4 mg hard capsule	thorntonross@medinformation.co.uk	Dutasteride/Tamsulosin hydrochloride 0.5mg/0.4mg hard capsule - Summary of Product Characteristics (SmPC) - (emc) 15619	thorntonross@medinformation.co.uk
Zentiva Pharma UK Ltd	Dutrozen 0.5 mg / 0.4 mg hard capsules (Dutasteride + Tamsulosin 0.5mg/0.4mg capsules)	PV-United-Kingdom@zentiva.com	https://www.medicines.org.uk/emc/product/11305	UKMedInfo@zentiva.com