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7th July 2025

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

Dear Healthcare professional,

Azure Pharmaceuticals, Bernardette Rossi (on behalf of CPSU), GlaxoSmithKline (Ireland) Limited, Heaton k.s, JV Healthcare, Laboratoires Bailleul S.A., Lavipharm S.A., Mint Health Ltd, Neofarma Pharmaceuticals Ltd, NM Pharma Ltd, Pharma.mt Ltd in agreement with the European Medicines Agency and the Malta Medicines Authority 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 androgenic 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 products containing finasteride 1mg to highlight the risks of depressed mood, depression, suicidal ideation and sexual dysfunction reported with finasteride**
- **Despite there is insufficient evidence to establish a direct association of suicidal ideation with dutasteride, based on the common mechanism of action of 5-alpha reductase inhibitors, patients 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 including combination with tamsulosin is indicated for the management of symptomatic benign prostatic hyperplasia. For finasteride- and dutasteride-containing 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 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 available data, the EMA confirms suicidal ideation being 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 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 (known risk 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.

The patient card can be accessed from https://medicinesauthority.gov.mt/rmm

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

The review also confirmed suicidal ideation being 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, **based on the evidence for another systemic 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.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Malta Medicines Authority ADR reporting form available online at http://medicinesauthority.gov.mt/adrportal and sent to Pharmacovigilance Section at Post-Licensing Directorate, Malta Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN or sent by email to: postlicensing.medicinesauthority@gov.mt

Company contacts point

Company	Product Name	Email	Phone
Pharma.MT Ltd	Finasteride Stada 1mg film-coated tablets	pharmacovigilance@pharmamt.com	+356 7953 4913
Glaxo SmithKline Ireland Limited	Combodart 0.5 mg / 0.4 mg hard capsules	mt.safety@gsk.com	+356 80065004
Glaxo SmithKline Ireland Limited	Avodart 0.5mg soft capsules	mt.safety@gsk.com	+356 80065005
JV Healthcare	Finasteride 5mg film-coated tablets	info@jvpharma.eu	+356 21437551
JV Healthcare	Combodart 0.5 mg/0.4 mg hard capsules	info@jvpharma.eu	+356 21437551
Neofarma Pharmaceuticals Ltd.	Avodart 0.5mg soft capsules	info@neofarma.com.mt / regulatory@inv.mt	+356 20109494
Neofarma Pharmaceuticals Ltd.	Combodart 0.5mg / 0.4mg hard capsules	info@neofarma.com.mt / regulatory@inv.mt	+356 20109494
Neofarma Pharmaceuticals Ltd.	Combodart 0.5mg / 0.4mg hard capsules	info@neofarma.com.mt / regulatory@inv.mt	+356 20109494
Neofarma Pharmaceuticals Ltd.	Finasteride Aurobindo 5mg film-coated tablets	info@neofarma.com.mt / regulatory@inv.mt	+356 20109494
Neofarma Pharmaceuticals Ltd.	Propecia 1mg, film-coated tablets	info@neofarma.com.mt / regulatory@inv.mt	+356 20109494
Laboratoires Bailleul S.A.	Finasteride Biorga 1mg film-coated tablets	vigilances@bailleul.com	+356 21433330 / +356 9942 6611
Lavipharm S.A.	Prostatyl	tchavela@lavipharm.com	+30 210 6691398
Central Procurement & Supplies Unit	Finasteride 5mg Film-Coated Tablet	bernardette.rossi@gov.mt	+356 79538319
Central Procurement & Supplies Unit	Finasteride 5mg Tablets	bernardette.rossi@gov.mt	+356 79538319
Azure Pharmaceuticals	Dutasteride/Tamsulosin Hydrochloride 0.5mg/0.4mg hard capsules	chiara.bilocca@azure-pharma.com	+356 99447352
Mint Health Ltd	Finasteride Zentiva 5mg film-coated tablets	pharmacovigilancemt@mint.com.mt	+356 79310592
NM Pharma Ltd	Finasteride Aurobindo 5mg film-coated tablets	pv@nmpharma.com.mt	+356 79310592
Heaton k.s., Na Pankráci 332/14, 140 00 Prague, Czech Republic	Atucare 0.5 mg/0.4 mg hard capsules	klara.svedova@heaton.cz	+420 245 019 282

Yours faithfully,

Post-Licensing Directorate

Medicines Authority

Disclaimer

This Direct Healthcare Professional Communication has been submitted to you on behalf of Azure Pharmaceuticals, Bernardette Rossi (on behalf of CPSU), GlaxoSmithKline (Ireland) Limited, Heaton k.s, JV Healthcare, Laboratoires Bailleul S.A., Lavipharm S.A., Mint Health Ltd, Neofarma Pharmaceuticals Ltd, NM Pharma Ltd, Pharma.mt

The MMA receives the relevant contact details from both the Medical Council and the Pharmacy Council. Should you wish to amend your details including address, you are asked to contact the Medical Council or Pharmacy Council directly, as may apply.