EMA starts safety review of medicines containing finasteride and dutasteride

04/10/2024 | Circular Number P11/2024

Information on Finasteride and Dutasteride

EMA started a review of medicines containing finasteride and dutasteride following concerns regarding suicidal ideation (suicidal thoughts) and behaviours.

- Tablets containing 1 mg of finasteride and finasteride solution for application to the skin are used to treat the early stages of androgenic alopecia (hair loss due to male hormones) in men aged 18 to 41 years. Tablets containing 5 mg finasteride and capsules containing 0.5 mg dutasteride are used to treat men with benign prostatic hyperplasia (BPH), a condition in which the prostate is enlarged and can cause problems with the flow of urine.
- Finasteride and dutasteride work by preventing an enzyme called 5-alpha reductase (5-AR) to change 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.
- In the EU, finasteride- and dutasteride-containing medicines are available as tablets or spray solutions under various trade names such as Propecia, Proscar, Fynzur, Avodart, Combodart, Dutaglandin, Androfin, Dupro, Duster, Andropecia, Adadut, Androfin, Prosterid, Finpros, Tadusta, Gefina, Dutascar, Finural, Finaristo, Finapil, Prosmin, Finapuren, Capila, Finahair, Duodart, Dutalosin and others.

  The following products are authorised via various procedures.

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
Finasteride 1milligram	'Finasteride 1mg film-coated Tablets'	Film-coated tablet	POM	MA807/06901	Aurobindo Pharma (Malta) Limited'
Finasteride 1milligram	'Finasteride Biorga 1 mg film-coated tablets '	Film-coated tablet	POM	MA1106/00301	Laboratoires Bailleul S.A'
Finasteride 1milligram	'FINASTERIDE STADA 1 mg film-coated tablets '	Film-coated tablet	POM	AA912/01401	Pharma MT
Finasteride 5 milligram	'Finasteride 5mg film-coated tablets'	Film-coated tablet	POM	PI770/13501A	JV Healthcare Limited

Finasteride 5 milligram	'Finasteride Aurobindo 5 mg film-coated tablets'	Film-coated tablet	POM	MA807/10001	Aurobindo Pharma (Malta) Limited
Finasteride 5 milligram	'Finasteride 5mg Film-Coated Tablet'	Film-coated tablet	POM	AA565/59101	Central Procurement & Supplies Unit
Finasteride 5 milligram	'Finasteride 5mg Tablets'	Tablet	POM	AA565/59102	Central Procurement & Supplies Unit
Finasteride 5 milligram	'Finasteride Aurobindo 5 mg film-coated tablets '	Film-coated tablet	POM	PI908/11501A	NeoFarma Pharmaceuticals Limited
Finasteride 5 milligram	'Finasteride Aurobindo 5mg film-coated tablets'	Film-coated tablet	POM	PI1438/08101A	NM Pharma Limited
Finasteride 5 milligram	'Finasteride Zentiva 5 mg film-coated tablets'	Film-coated tablet	POM	AA1173/08001	Mint Health Ltd
Finasteride 5 milligram	'Finasteride Ascend 5 mg film-coated tablets'	Film-coated tablet	POM	MA1431/00401	Ascend GmbH c/o Pollux Business Center GmbH
Dutasteride 0.5 milligram	'Dutasteride Galenicum 0.5 mg soft capsules'	Soft capsule	POM	MA255/00801	Galenicum Health, S.L.U
Dutasteride 0.5 milligram	'Dutasteride Doc Generici 0.5 mg soft capsules'	Soft capsule	POM	MA1066/00201	Doc Generici srl
Dutasteride 0.5 milligram	'Dutasteride 0.5mg soft capsules'	Soft capsule	POM	MA1269/03801	Accord Healthcare Ireland Ltd
Dutasteride 0.5 milligram	'Dutasteride Galenicum Health 0.5 mg soft capsules '	Soft capsule	POM	MA255/02601	Galenicum Health, S.L.U
Dutasteride 0.5 milligram	'Dutasteride Mylan 0.5mg Soft Capsules '	Soft capsule	POM	MA1270/02501	Mylan Ireland Limited

Information from the EMA about the safety concern

- EMA started a review of medicines containing finasteride and dutasteride following concerns regarding suicidal ideation (suicidal thoughts) and behaviours.
- Medicines containing finasteride and dutasteride taken by mouth have a known risk of psychiatric side effects, including depression. Suicidal ideation has also recently been added as a possible side effect of unknown frequency in the product information for Propecia and Proscar, the first two finasteride-containing medicines authorised in several

countries of the European Union (EU). To minimise the risks, measures are already in place for finasteride medicines, including warnings in the product information for healthcare professionals to monitor patients for psychiatric symptoms and stop treatment if symptoms occur, and recommendations for patients to seek medical advice if they experience psychiatric symptoms.

- During the review, PRAC will assess all available data linking finasteride and dutasteride to suicidal ideation and behaviours. It will also evaluate the impact of suicidal ideation and behaviours on the benefit-risk balance of these medicines, taking into consideration the conditions they are used to treat.
- EMA will now review all available data on suicidal ideation and behaviours with finasteride and dutasteride and issue a recommendation on whether the marketing authorisations for these medicines should be maintained, varied, suspended or withdrawn across the EU.

Information for patients

- Medicines containing finasteride and dutasteride taken by mouth have a known risk of psychiatric side effects, including depression. Suicidal ideation has also recently been added as a possible side effect of unknown frequency in the product information for Propecia and Proscar, the first two finasteride-containing medicines authorised in several countries of the European Union (EU).
- Seek medical advice if you experience psychiatric symptoms.
- If you have any questions or concerns about your medicines, speak to your doctor or pharmacist.

Information for Healthcare Professionals

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Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance with finasteride and dutasteride- containing medicines. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to: Sir Temi Żammit 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 Malta 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 Malta 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:

We thank you for your interest and look forward to hearing your opinion.

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Pharmacovigilance Section

Post-Licensing Directorate

Medicines Authority

Sir Temi Żammit Buildings

Malta Life Sciences Park

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