4 October 2024
EMA/452263/2024

EMA starts safety review of medicines containing finasteride and dutasteride

Review assesses data related to suicidal thoughts and behaviours

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.

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.

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.

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a recommendation on whether the marketing authorisations for these medicines should be maintained, varied, suspended or withdrawn across the EU.

More about the medicines

Medicines containing finasteride (1 mg tablets or spray to be applied to the skin) are authorised in various EU Member States to prevent hair loss and stimulate hair growth in men aged 18 to 41 years with early-stage androgenic alopecia (hair loss due to male hormones). In addition, medicines

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

containing finasteride (5 mg tablets) and dutasteride (0.5 mg 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 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.

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.

More about the procedure

The review of medicines containing finasteride and dutasteride has been initiated at the request of the French medicines agency (ANSM), under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendations will then be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a position. The CMDh is a body representing EU Member States as well as Iceland, Liechtenstein and Norway. It is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.