2 October 2024
Media and Public Relations

News announcement

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 30 September-3 October 2024

Review of medicines containing finasteride and dutasteride started

Review assesses data related to suicidal thoughts and behaviours

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

Tablets containing 1 mg 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.

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 the two first finasteride-containing medicines authorised in several countries of the European Union (EU), Propecia and Proscar.

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, stop treatment if symptoms occur, and recommendations for patients to seek medical advice if they experience psychiatric symptoms.

More information is available in EMA's public health communication.

New safety information for healthcare professionals: Risk of medication error due to change of dosing syringe for Keppra and Levetiracetam UCB oral solution

Keppra and Levetiracetam UCB are medicines used to treat epilepsy, on its own or as an add-on to another anti-epileptic medicine.

The PRAC discussed a direct healthcare professional communication (DHPC) regarding a change to the dosing syringe included in the product packaging of Keppra and Levetiracetam UCB 100 mg/ml oral solution intended for use in children aged 6 months to 4 years (150ml bottle). The 3ml dosing syringe is being replaced with a 5ml dosing syringe. The DHPC will inform healthcare professionals of the potential risk of medication error due to the change in the volume of the dosing syringe.

When prescribing and dispensing levetiracetam (Keppra and Levetiracetam UCB) oral solution with the new 5ml syringe, healthcare professionals should inform caregivers about the change in the volume of the dosing syringe. Caregivers should be informed that while the new 5ml syringe is graduated every 0.1ml, it has additional graduations of 0.25ml compared to the 3ml syringe. Caregivers should be counselled on the correct dose and how to measure the correct dose with the 5ml syringe. Caregivers should be advised to read the instructions in the Package Information Leaflet on how to recognize signs and symptoms of a levetiracetam overdose and what to do in this situation.

The DHPC for Keppra and Levetiracetam UCB will be forwarded to EMA's human medicines committee (CHMP). When adopted, the DHPC will be disseminated to healthcare professionals by the marketing authorisation holders, according to an agreed communication plan, and published on the Direct healthcare professional communications page and in national registers in EU Member States.

PRAC statistics: October 2024

Glossary:

Safety signal assessments. A safety signal is information which suggests a new potentially causal association, or a new aspect of a known association between a medicine and an adverse event that warrants further investigation. Safety signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. More information can be found under 'Signal management'.

Periodic safety update reports, abbreviated as PSURs, are reports prepared by the marketing authorisation holder to describe the worldwide safety experience with a medicine in a defined period after its authorisation. PSURs for medicinal products that contain the same active substance or the same combination of active substances but have different marketing authorisations and are authorised in different EU Member States, are jointly assessed in a single assessment procedure. More information can be found under 'Periodic safety update reports: questions and answers'.

Risk management plans, abbreviated as RMPs, are detailed descriptions of the activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicines. Companies are required to submit an RMP to EMA when applying for a marketing authorisation. RMPs are continually updated throughout the lifetime of the medicine as new information becomes available. More information is available under 'Risk-management plans'.

Post-authorisation safety studies, abbreviated as PASSs, are studies carried out after a medicine has been authorised to obtain further information on its safety, or to measure the effectiveness of risk-management measures. The PRAC assesses the protocols (aspects related to the organisation of a study) and the results of PASSs. More information can be found under 'Post-authorisation safety studies'.

Referrals are procedures used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral related to safety of medicines, the PRAC is requested by a Member State or the European Commission to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the EU. More information can be found under referral procedures.

Notes

1. This press release, together with all related documents, is available on the Agency's website at: www.ema.europa.eu

2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu