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Review of amfepramone medicines started

EMA has started a review of obesity medicines that contain amfepramone. These medicines are authorised in some EU countries as treatment for patients with obesity (body mass index of at least 30 kg/m^2) in whom other weight-reduction methods have not worked on their own. Amfepramone medicines are authorised to be used for 4 to 6 weeks and no longer than 3 months.

A review by EMA's safety committee (PRAC) of the recent periodic safety update report for amfepramone raised concerns that require further evaluation. The concerns include heart problems, high blood pressure in the lungs, use of the medicine for longer than 3 months, exceeding the maximum recommended dose, and use during pregnancy despite recommendations against such use.

As a result of these concerns, the Romanian medicines agency requested a review of the safety of amfepramone medicines in the context of the medicines' benefits. EMA will communicate the PRAC's recommendations once the review has concluded.

More about the medicine

Amfepramone is a sympathomimetic, which means that it acts in the brain and causes effects that are similar to those of adrenaline. Such medicines reduce a feeling of hunger. Within the EU, amfepramone medicines are authorised in Denmark, Germany and Romania under various trade names including Regenon and Tenuate retard.

EMA had previously reviewed the benefits and risks of medicines such as amfepramone in 1996.

More about the procedure

The review of amfepramone medicines has been initiated at the request of Romania, 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. As amfepramone-containing medicines are all authorised nationally, the PRAC recommendations will 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

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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.