10 June 2022
EMA/574597/2022

EMA recommends withdrawal of marketing authorisation for amfepramone medicines

EMA's safety committee (PRAC) has recommended the withdrawal of EU marketing authorisations for amfepramone obesity medicines.

The recommendation follows a review which found that measures to restrict the use of these medicines for safety reasons have not been sufficiently effective. It found that the medicines were being used for longer than the recommended maximum period of 3 months, thereby potentially increasing the risk of serious side effects, such as pulmonary arterial hypertension (high blood pressure in the arteries of the lungs) and dependency. The medicines were also being used in patients with a history of heart disease or psychiatric disorders, increasing their risk of heart and psychiatric problems. In addition, there was evidence of use during pregnancy, which could pose risks to the unborn baby.

The review considered all available information relating to these concerns, including data from two studies on the use of amfepramone medicines in Germany and in Denmark. In addition, the PRAC received advice from a group of experts, comprising endocrinologists, cardiologists and a patient representative.

The PRAC considered introducing further measures to minimise the risk of side effects but could not identify any that would be sufficiently effective. The PRAC therefore concluded that the benefits of amfepramone medicines do not outweigh their risks and recommended that the medicines be removed from the market in the EU.

Information for patients

- EMA is recommending that amfepramone obesity medicines should no longer be available in the EU because they are not always used as recommended.
- Inappropriate use can cause serious side effects, such as increased blood pressure in arteries of the lungs, heart disease, dependency, psychiatric problems and harm to the unborn baby.
- The benefits of using these medicines are limited as people regain weight after the short-term treatment.
- Other obesity treatment options are available. Contact your doctor to discuss which treatment would be suitable for you.
- If you have other questions or concerns about amfepramone medicines, speak to your doctor or pharmacist.

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Information for healthcare professionals

- EMA is recommending the withdrawal of the EU marketing authorisations for amfepramone-containing medicines for the treatment of obesity.
- A review of available data has found that amfepramone medicines continue to be used outside the current risk minimisation measures included in the product information.
- Inappropriate use may increase the risk of serious adverse effects, including cardiovascular disease, pulmonary arterial hypertension, dependency and psychiatric disorders, as well as harmful effects if used during pregnancy.
- There is limited efficacy of a short-term treatment as patients usually regain weight following cessation of treatment.
- Healthcare professionals should advise patients about other treatment options.

A direct healthcare professional communication (DHPC) will be sent in due course to healthcare professionals prescribing or dispensing the medicine and published on a dedicated page on the EMA website.

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.

Amfepramone medicines were authorised in Denmark, Germany and Romania 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 were authorised to be used for 4 to 6 weeks and no longer than 3 months.

Within the EU, amfepramone medicines were available under the following trade names: Amfepramon-Hormosan 25 mg Weichkapseln, Amfepramon-Hormosan 60 mg Retardkapseln, Regenon, Tenuate Retard 75 mg retardtablette and Regenon 25 mg capsule moi.

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 has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which has made a set of recommendations.

The PRAC recommendations will now be sent 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.

This review follows previous reviews on the benefits and risks of appetite-suppressing medicines (including amfepramone) in 1996 and 1999.