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Withdrawal of marketing authorisations for fenspiride medicines

On 16 May 2019, EMA's safety committee (PRAC) recommended that the marketing authorisations for fenspiride medicines be revoked, so the medicines can no longer be marketed in the EU. This follows a review that confirmed that these cough medicines could cause heart rhythm problems.

The PRAC considered all the available evidence in its review. This included cases of QT prolongation and torsades de pointes (abnormalities of the heart's electrical activity that may lead to heart rhythm disturbances) in patients using these medicines, results of laboratory studies, data from published literature and stakeholder input.

Heart rhythm problems can be serious and occur suddenly, and it is not feasible to identify in advance the patients who may be at risk of these problems with fenspiride. In contrast, fenspiride medicines are used to treat non-serious cough. Therefore, the PRAC considered that these medicines should no longer be marketed.

The PRAC recommendation was adopted by the CMDh[1] by consensus and will be implemented directly at national level.

Information for patients

- Cough medicines containing fenspiride will no longer be marketed in the EU because of data showing a risk of sudden, serious heart rhythm problems.
- You should stop taking these medicines and contact your doctor or pharmacist for advice on alternative treatments, if needed. You can check the ingredients of your medicine in the package leaflet accompanying the medicine.
- Patients are only at risk of heart rhythm problems with fenspiride while they are taking these medicines.
- If you have any concerns about your medicine, discuss them with your doctor or pharmacist.
- Return unused medicines to your pharmacy for appropriate disposal.

[1] Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

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

Information for healthcare professionals

- Healthcare professionals should no longer prescribe fenspiride medicines and should advise their patients to stop taking fenspiride medicines.
- The withdrawal of the marketing authorisations of fenspiride medicines is based on case reports and nonclinical studies (including hERG channel binding) that showed that fenspiride can cause QT prolongation and has proarrhythmia potential (could cause triggering or worsening of arrhythmia) with the associated risk of torsades de pointes.
- Given the authorised uses of fenspiride for symptomatic treatment only and the seriousness of the safety concern, the benefit-risk balance of these medicines is negative for the currently authorised uses.

More about the medicines

Fenspiride medicines are available as syrup or tablets and used in adults and children from the age of 2 years to relieve cough resulting from lung diseases. In the EU, fenspiride medicines have been authorised via national procedures in Bulgaria, France, Latvia, Lithuania, Poland, Portugal and Romania and are available under various brand names (Elofen, Epistat, Eurefin, Eurespal, Fenspogal, Fosidal, Kudorp, Pneumorel, Pulneo, Еуреспал and Сиресп).

More about the procedure

The review of fenspiride was initiated on 14 February 2019 at the request of France, under Article 107i of Directive 2001/83/EC. At that time, the Pharmacovigilance Risk Assessment Committee (PRAC) recommended that supply of fenspiride medicines be suspended as a precautionary measure while the review was ongoing.

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

The PRAC recommendation was sent to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which adopted it by consensus on 29 May 2019. 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.

The PRAC recommendation will now be implemented by EU Member States, Iceland, Lichtenstein and Norway.