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Suspension of fenspiride medicines due to potential risk of heart rhythm problems

EMA's safety committee (PRAC) has recommended an EU-wide suspension of fenspiride medicines, used in children and adults to relieve cough caused by lung diseases.

The suspension is a precautionary measure to protect patients while the PRAC reviews the risk of QT prolongation and torsades de pointes (abnormalities of the heart's electrical activity that may lead to heart rhythm disturbances).

Cases of heart rhythm problems had been reported in patients who had taken these medicines in the past. To explore the potential link between fenspiride and these heart rhythm problems, animal studies were carried out which now show that fenspiride has the potential to prolong QT in humans.

The PRAC will now examine all the available evidence and make recommendations on the action to be taken on marketing authorisations for fenspiride medicines across the EU. Once the review is concluded, EMA will communicate further and provide updated guidance to patients and healthcare professionals.

Information for patients

- Safety data indicate that cough medicines containing fenspiride could cause sudden serious heart rhythm problems.
- While authorities review all the evidence, patients are advised to stop taking these medicines.
- Patients are only at risk of heart rhythm problems with fenspiride while they are taking these medicines.
- If you are taking a cough medicine containing fenspiride, contact your doctor or pharmacist for advice on alternative treatments, if needed.
- If you have any concerns about your medicine, discuss them with your doctor or pharmacist.

Information for healthcare professionals

- As a precaution and while the review is ongoing, healthcare professionals should advise their patients to stop taking fenspiride medicines.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

- The provisional suspension of fenspiride medicines is based on recent nonclinical studies (hERG channel binding and in vitro animal model studies) that showed that fenspiride has the potential to increase QT intervals in humans. These data were supportive of a previously suspected link between fenspiride and QT prolongation/torsades de pointes in humans, which was based on a limited number of case reports.
- Given the authorised use of fenspiride for symptomatic treatment only and the seriousness of QT prolongation, the medicines are provisionally suspended pending the results of an urgent EU safety review.
- Healthcare professionals will be informed in writing about the suspension, and further information will be provided as needed and once the review has concluded.

The Agency invites all stakeholders (e.g. healthcare professionals, patients' organisations, and the general public) to submit data relevant to this procedure. Full details are available in the 'data submission' section.

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 has been initiated at the request of France, under Article 107i 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. While the review is ongoing the PRAC has recommended suspending the medicines to protect public health.

Since fenspiride medicines are all authorised nationally, once the PRAC concludes its review, its 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 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.