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Review of flupirtine-containing medicines started

Medicines still being used outside current restrictions and cases of liver damage have continued to be reported

The European Medicines Agency (EMA) has started a new review of the benefits and risks of flupirtine-containing medicines for pain relief.

The review was requested by the German medicines authority, the Federal Institute for Drugs and Medical Devices (BfArM), and follows a previous EMA review[1] in 2013 which introduced measures to restrict the use of these medicines because of reports of serious liver problems associated with their use.

As part of the measures from the earlier review, flupirtine use was limited to no more than 2 weeks in patients who could not use other pain treatments and tests of liver function were introduced before and during treatment. EMA also requested studies to show whether these restrictions were effective in reducing the risks. Results from some studies have now become available and suggest that, although the number of treated patients has gone down, the medicine is still being used outside the restrictions introduced in 2013. Furthermore, cases of serious liver damage associated with this medicine have continued to be reported.

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has therefore begun a further review to determine how the latest available data affects the balance of benefits and risks for these medicines and to decide whether additional regulatory action should be taken. While the review is ongoing, patients who have any concerns about their medication should speak to their doctor or pharmacist.

More about the medicine

Flupirtine is an analgesic (a medicine for pain relief) used to treat acute (short-lived) pain for up to 2 weeks, in patients who cannot use other pain medicines such as opioids or nonsteroidal anti-inflammatory medicines (NSAIDs). Flupirtine works as a 'selective neuronal potassium channel opener'.

[1] EMEA/H/A-107i/1363

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This means that it opens specific pores on the surface of nerve cells called potassium channels. The opening of these channels reduces the excessive electrical activity that leads to many pain states.

Flupirtine-containing medicines have been authorised since the 1980s and are currently available in the following EU Member States: Austria, Estonia, Germany, Latvia, Lithuania, Luxembourg, Poland, Portugal, and Slovakia. They are available under several trade names and in different formulations.

More about the procedure

The review of flupirtine has been initiated at the request of Germany, 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 flupirtine-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 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.