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PRAC recommends that the marketing authorisation of the painkiller flupirtine be withdrawn

Serious liver problems continued to be reported despite previous restrictions in use

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended that, the marketing authorisation for the painkiller flupirtine be withdrawn. This means that the medicine will no longer be available in the EU.

The review of flupirtine follows a previous EMA review in 2013 which introduced measures to restrict the use of the medicine because of reports of serious liver problems.

As part of these measures, flupirtine use was limited to no more than 2 weeks in patients with acute pain who could not use other painkillers, and weekly tests of liver function were to be carried out during treatment. EMA also requested studies to assess whether these restrictions were followed in clinical practice and were effective in reducing the risk of liver problems.

The PRAC has now reviewed the results from these studies together with the currently available data on benefits and risks from clinical trials and case reports, including cases of serious liver damage reported since the 2013 review. Based on this review, the PRAC has concluded that the restrictions introduced in 2013 have not been sufficiently followed in clinical practice, and cases of serious liver injury still occurred including liver failure. The Committee explored the possibility of introducing further measures but could not identify any that would increase adherence to the restrictions and adequately reduce the risk of liver problems.

PRAC therefore considered that patients taking flupirtine-containing medicines continue to be exposed to serious risks which outweigh the benefits of these medicines and recommended the withdrawal of their marketing authorisations. Alternative treatment options are available.

The PRAC recommendation will be considered by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position.

Patients and healthcare professionals should note that the marketing authorisations of flupirtine-containing medicines are not yet withdrawn and a final decision is pending. Once the procedure is finalised, further details including advice for patients and healthcare professionals will be published. Healthcare professionals in the EU countries where flupirtine is marketed will also receive a letter with detailed information on the appropriate actions to be taken. In the meantime patients who have any questions should speak to their doctor or pharmacist.

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More about the medicine

Flupirtine is an analgesic (a medicine for relieving pain) 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'. This means that it opens specific pores on 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: 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 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. As flupirtine-containing medicines are all authorised nationally, 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.