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Review of flupirtine-containing medicines started

The European Medicines Agency has started a review of flupirtine-containing medicines due to concerns of liver problems associated with the use of these medicines for short- and long-term pain relief.

The review was triggered by the German medicines agency, the Federal Institute for Drugs and Medical Devices (BfArM), following an increasing number of reports of liver problems associated with the use of flupirtine, which ranged from the asymptomatic increase in liver enzymes to liver failure. In Germany, 330 reports of liver problems have been recorded in the database of adverse drug reactions, 15 of which had a fatal outcome or resulted in liver transplantation.[1] The German agency also noted a lack of data supporting the effectiveness of flupirtine in long-term pain.

The European Medicines Agency will review all available data on the safety of flupirtine-containing medicines, particularly liver reactions, in order to assess any impact on the benefit-risk balance of these medicines.

While the review is ongoing patients should speak to their doctor or pharmacist if they have any questions or concerns.

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 under the "data submission" tab.

More about the medicine

Flupirtine is an analgesic (a medicine for pain relief) used to treat acute (short-lived) and chronic (long-term) pain, such as pain associated with muscle tension, cancer pain, dysmenorrhoea (period pain) and pain following orthopaedic surgery or injuries.

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

[1] Patient exposure to flupirtine was estimated to be 28.1 million defined daily doses in Germany in 2011.

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Flupirtine was first introduced as an alternative analgesic to opioids and NSAIDs. Subsequently, multiple other actions such as muscle relaxation were identified. Flupirtine works as a 'selective neuronal potassium channel opener'. 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.

More about the procedure

The review of flupirtine-containing medicines has been initiated at the request of Germany, 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, which will make a set of recommendations. As flupirtine-containing medicines are all authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh is a regulatory body that represents national medicines regulatory authorities of the EU Member States.