



**CONFIDENTIAL – EMBARGO: 26 September 2006, 13h00 London time**

## **Draft Questions and Answers on ketoprofen, ketorolac and piroxicam**

As part of its continuous monitoring of medicines, the EMEA has further examined three non-selective non-steroidal anti-inflammatory drugs (NSAIDs): ketoprofen, ketorolac and piroxicam. At this point in time, doctors and patients are advised to continue treatment as before, keeping in mind that they should use the lowest effective dose for the shortest possible duration to control symptoms. A separate question and answer document on the ongoing review of non-selective NSAIDs is available [[here](#)].

### **What are ketoprofen, ketorolac and piroxicam?**

Ketoprofen and piroxicam are non-selective NSAIDs that are widely used in the treatment of inflammatory conditions, such as arthritis and other painful conditions. Ketorolac is also a non-selective NSAID, which is usually used for short-term pain relief such as after an operation.

### **What was the outcome of the review of the benefits and risks of these three compounds?**

The Agency's Committee for Medicinal Products for Human Use (CHMP) looked at the overall balance of benefits and risks of each of these compounds.

The conclusions were that there should be stronger warnings for cardiovascular safety, gastrointestinal safety and skin reactions for all three compounds, to promote more cautious use. The product information should be amended with certain key elements, which can be found [here](#). They also concluded that:

- The benefits of **ketoprofen** outweigh its risks for daily doses up to a maximum of 200 mg.
- The benefits of **ketorolac** outweigh its risks in its approved short-term use.
- **Piroxicam** may have a less favourable gastrointestinal safety profile and a higher risk of skin reactions than that of other non-selective NSAIDs and a formal assessment procedure should be started.

### **What happens next?**

The European Commission has asked the CHMP to review piroxicam to assess its benefit-risk profile. This review will be carried out under an 'Article 31 referral', and will result in a decision that is binding in all EU Member States.

Until the outcome of this referral is known, the CHMP is recommending that the above warnings regarding cardiovascular and gastrointestinal safety and skin reactions be observed.

### **What is the current advice for patients and prescribers?**

- Patients and prescribers should continue to use medicines containing ketoprofen, ketorolac and piroxicam as currently recommended.
- Doctors and patients should always use the lowest effective dose for the shortest possible duration to control symptoms.
- Doctors should continue to prescribe NSAIDs on the basis of the overall safety profiles of the medicines as set out in the product information, and individual risk factors.
- Patients who have concerns or questions should talk to their doctor or pharmacist.