European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends restricted use for piroxicam

The European Medicines Agency (EMEA) has recommended restrictions on the use of piroxicam-containing medicinal products because of the risk of gastrointestinal side effects and serious skin reactions. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that piroxicam should no longer be used for treatment of short-term painful and inflammatory conditions. Piroxicam can still be prescribed for the symptomatic relief of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. However it should not be the first choice of non-steroidal anti-inflammatory drug (NSAID) treatment in these conditions.

Prescription of piroxicam should always be initiated by a physician experienced in the treatment of patients with inflammatory or degenerative rheumatic diseases and treatment should be used in the lowest dose (no more than 20 mg per day) and for the shortest duration possible. In any case, the treatment should be reviewed after the first 14 days of starting.

In addition, the CHMP recommended new contraindications and strengthened warnings for piroxicam, further details of which are provided in a separate question-and-answer document.

Topical medicines containing piroxicam are not concerned by these restrictions.

Further to the request of the European Commission, the CHMP initiated a full assessment of the benefits and risks of piroxicam in September 2006, because a review of non-selective NSAIDs showed that piroxicam could be associated with a higher risk of gastrointestinal side effects and serious skin reactions than other non-selective NSAIDs.

The CHMP recommendations will now be forwarded to the European Commission for adoption of a legally binding decision, applicable in all EU Member States.

--ENDS--

NOTES

1. The safety review was conducted in accordance with Article 31 of the Community code on human medicinal products (Directive 2001/83/EC as amended).
2. More information about the recommendations for piroxicam is available in a separate question-and-answer document.
3. A press release announcing the start of the procedure for piroxicam can be found here: http://www.emea.europa.eu/pdfs/general/direct/pr/37869506en.pdf .
4. More information about the review of NSAIDs can be found here: http://www.emea.europa.eu/pdfs/human/press/pr/29896405en.pdf .
5. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: http://www.emea.europa.eu.

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