



European Medicines Agency
Press office

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Questions and Answers on the review of non-selective NSAIDs

As part of its continuous monitoring of medicines, the European Medicines Agency has begun reviewing newly available safety data on non-selective NSAIDs. 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.

What are NSAIDs?

NSAIDs are non-steroidal anti-inflammatory drugs. They have been available on the market for many years and are important in the treatment of arthritis and other painful conditions.

Which NSAIDs are being looked at in this review?

There are many different types of NSAIDs, but this review is only looking at a group of compounds called non-selective NSAIDs. The non-selective NSAIDs being looked at are diclofenac, etodolac, ibuprofen, indomethacin, ketoprofen, ketorolac, meloxicam, nabumetone, naproxen, nimesulide and piroxicam. Non-selective NSAIDs are so-called because they act on all types of the cyclo-oxygenase enzyme, including one type that is involved in the inflammation process.

Why is the EMEA starting the review?

Following its review of NSAIDs in 2005, the EMEA has been monitoring closely this class of compounds. The Agency's Committee for Medicinal Products for Human Use (CHMP) has become aware of new safety data concerning non-selective NSAIDs, especially in long-term use, that signal a potential thrombotic risk (risk of heart attack or stroke). This review is initiated to evaluate the cardiovascular safety of non-selective NSAIDs as a group in the context of their overall benefit-risk profile.

The French national medicines agency, Agence française de sécurité sanitaire des produits de santé (Afssaps), has requested the CHMP to give its opinion on the cardiovascular safety of NSAIDs. The Afssaps is requesting the review under an 'Article 5(3) procedure'. This procedure is described in Article 5(3) of Regulation (EC) No 726/2004 and results in a CHMP scientific opinion, which will be made publicly accessible.

What happens next?

The Committee has begun reviewing available safety data from clinical and epidemiological studies. It will give a scientific opinion on the cardiovascular safety of non-selective NSAIDs during its next meeting of 16-19 October 2006, including recommendations on how to address any safety concerns that may be identified.

What is the current advice for patients and prescribers?

- Patients and prescribers should continue to use non-selective NSAIDs 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.

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