



European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency recommends restricted use of nimesulide-containing medicinal products

Finalising a review of the liver safety of systemic formulations of medicines containing nimesulide, the European Medicines Agency (EMA) has concluded that the benefits of these medicines outweigh their risks, but that there is a need to limit the duration of use and to restrict their use to ensure that the risk of patients developing liver problems is kept to a minimum.

Medicines containing nimesulide in systemic formulations are authorised in a number of European Union (EU) Member States to treat acute pain, and the symptoms of painful osteoarthritis and primary dysmenorrhoea (period pains).

The marketing authorisations for nimesulide-containing medicines were suspended by the Irish competent authority in Ireland on 15 May 2007, because of reports of serious side effects affecting the liver. After the Irish authority had notified the EMA about the suspension, the Committee for Medicinal Products for Human Use (CHMP) started an assessment of the hepatic safety of these medicines in June 2007 to reach a conclusion on whether the regulatory actions taken by Ireland should be implemented throughout the EU.

Having considered all of the available evidence, the CHMP concluded that the data did not support a suspension of all marketing authorisations in Europe. However, it also concluded that there was a need for the marketing authorisations to be changed, with the information provided to doctors and patients to be amended to limit the risk of liver injury.

The CHMP therefore recommended that treatment with nimesulide should be limited to a maximum of 15 days and that consequently all packs containing more than 30 doses (tablets or sachets) should be removed from the market. Doctors are advised to base their decision to prescribe nimesulide on an assessment of the individual patient's overall risks.

A European Commission Decision on this opinion will be issued in due course. The Decision will apply in all Member States.

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Notes:

1. More information about the review is available in a separate [question-and-answer document](#).
2. The full changes made to the information to doctors and patients are detailed [here](#).
3. Systemic formulations' are types of medicine that are given as a treatment throughout the body, such as tablets, solutions and suppositories.
4. The review of nimesulide was the first procedure initiated under Article 107 of the Community code relating to medicinal products for human use (Directive 2001/83/EC). This type of procedure is initiated in cases where a Member State withdraws, suspends or changes the marketing authorisation of a nationally authorised medicinal product as result of the evaluation of safety data. It provides for a harmonised European approach because the CHMP is asked to prepare an opinion on whether or not the regulatory actions should be implemented throughout the European Union.
5. Nimesulide is a non-selective non-steroidal anti-inflammatory drug (NSAID). It is marketed in the following EU Member States: Austria, Belgium, Bulgaria, the Czech Republic, Cyprus,

France, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia and Slovenia.

6. Nimesulide was reviewed previously by the CHMP because of concerns over the effects of the medicine on the liver. This review, which was concluded in December 2003, resulted in the CHMP recommending a number of restrictions, including limiting the maximum daily dose to 100 mg twice a day for a short a duration as possible, limiting its use to the treatment of acute pain, osteoarthritis ad dysmenorrhoea, contra-indicating its use in patients with liver problems, and the inclusion of warnings on the risk of serious liver reactions. More information about the previous review procedure can be found here:
<http://www.emea.europa.eu/htms/human/referral/2004.htm>
7. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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