



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 June 2011  
EMA/CHMP/486983/2011  
Press Office

## Press release

---

# European Medicines Agency concludes review of systemic nimesulide-containing medicines

## Use to be restricted to treatment of acute pain and primary dysmenorrhoea

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of systemic nimesulide-containing medicines continue to outweigh their risks in the treatment of patients with acute pain and primary dysmenorrhoea. However, these medicines should no longer be used for the symptomatic treatment of osteoarthritis.

Nimesulide is a non-steroidal anti-inflammatory drug (NSAID) that has been used to treat acute pain, painful osteoarthritis and primary dysmenorrhoea.

The Committee started a full assessment of the benefits and risks of nimesulide-containing medicines for systemic use at the request of the European Commission, because of ongoing concerns over their gastrointestinal and hepatic safety.

The CHMP reviewed results of epidemiological studies conducted by the marketing authorisation holder at the request of the Committee in 2007, all available reports on adverse drug reactions and data from the published literature.

The Committee noted that, in treatment of acute pain, nimesulide is as effective as other NSAID pain killers, such as diclofenac, ibuprofen and naproxen.

In terms of safety, the CHMP noted that nimesulide has the same risk of gastrointestinal toxicity as other NSAIDs. The CHMP concluded that nimesulide was associated with an increased risk of liver toxicity compared with other anti-inflammatory treatments. The Committee had previously imposed several restrictions on the use of systemic nimesulide in order to reduce risks of liver injury. Having reviewed all available data, the CHMP is now recommending, as a further restriction, that systemic nimesulide should no longer be used for the treatment of painful osteoarthritis. The Committee considered that the use of systemic nimesulide for the treatment of this chronic condition, would increase the risk of the medicines being used for long-term treatment, with a consequent increase in the risk of liver injury.



## Notes

---

1. This press release, together with all related documents, is available on the Agency's website.
2. Medicines containing nimesulide have been available since 1985 and are authorised in a number of Member States. They are only available with a prescription. Systemic nimesulide-containing medicines (capsules, tablets, suppositories and powder or granules for oral suspension) are available in the EU in Bulgaria, Cyprus, the Czech Republic, France, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia and Slovenia.
3. The review of nimesulide was conducted in the context of a formal review under Article 31 of Directive 2001/83/EC, initiated in January 2010 at the request of the European Commission. This type of procedure may be initiated in specific cases where the interest of the Community is involved, and foresees that the CHMP makes a recommendation on whether the marketing authorisation for a medicine should be maintained, changed, suspended or revoked. The expression 'Community interest' has a broad meaning but it refers particularly to the interests of public health in the Community, for example following concerns related to the quality, efficacy and/or safety of a medicine, that is authorised at the level of the Member States.
4. The CHMP's opinion has been sent to the European Commission for the adoption of a binding decision throughout the European Union.
5. A question-and-answer document on this review is available on the Agency's website.
6. The press release on the review of the CHMP initiated in 2007 is available on the Agency's website.
7. More information on the work of the European Medicines Agency can be found on its website: [www.ema.europa.eu](http://www.ema.europa.eu)

## Contact our press officers

---

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: [press@ema.europa.eu](mailto:press@ema.europa.eu)