6 December 2013
EMA/679264/2013/rev.2

Update of 5 December 2013:

Some marketing-authorisation holders for diacerein-containing medicines have requested a re-examination of the PRAC's November 2013 recommendation to suspend these medicines. Upon receipt of the grounds of the request, the PRAC will re-examine its recommendation and issue a final recommendation.

PRAC recommends suspension of diacerein-containing medicines

Committee cites concerns over gastro-intestinal side effects and liver toxicity

On 7 November 2013, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) recommended the suspension of diacerein-containing medicines across the EU. This followed a review which concluded that the benefits of diacerein, used to treat symptoms of osteoarthritis and other degenerative joint diseases, did not outweigh its risks, particularly the risk of severe diarrhoea and potentially harmful effects on the liver.

The review was conducted at the request of the French medicines agency (ANSM) over concerns about the frequency and severity of gastro-intestinal side effects such as diarrhoea and liver disorders. In addition, the French agency considered the evidence of diacerein's benefit in osteoarthritis to be weak.

Although diacerein is known to cause diarrhoea as a side effect, the PRAC concluded that there was a high number of cases, particularly of severe diarrhoea, which sometimes led to complications. The Committee was also concerned about liver problems that had been reported in some patients taking the medicine.

With regard to benefits, the PRAC considered that the available data showed the benefits of diacerein to be limited and it concluded that the benefits did not outweigh its risks. The PRAC therefore recommended that diacerein-containing medicines be suspended in the EU until convincing evidence of a positive benefit-risk balance in a specific patient population is provided.

The PRAC recommendation will now be sent to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) for consideration at its meeting on 16-18 December 2013.[1]

[1] The companies that market diacerein have the right to ask for a re-examination of the PRAC recommendation within 15 days of receipt of the PRAC recommendation, which would delay the expected time of finalisation of this review.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7129
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

More about the medicine

Diacerein belongs to a class of substances called anthraquinones. It is a slow-acting medicine that blocks the actions of interleukin-1 beta, a protein involved in the cartilage destruction and inflammation which play a role in the development of symptoms of degenerative joint diseases such as osteoarthritis.

Diacerein-containing medicines are taken by mouth and are currently authorised in the following EU Member States: Austria, Czech Republic, France, Greece, Italy, Portugal, Slovakia and Spain.

More about the procedure

The review of diacerein-containing medicines was initiated on 29 November 2012 at the request of the French medicines agency under Article 31 of Directive 2001/83/EC.

The review has been conducted by the Pharmacovigilance Risk Assessment Committee (PRAC). As the review only covers nationally authorised medicines, the PRAC recommendations will now be forwarded to Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh, a body representing EU Member States, is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.

If the CMDh position is agreed by consensus, the agreement will be implemented directly by the Member States where the medicines are authorised. Should the CMDh position be adopted by majority vote, the CMDh position will be sent to the European Commission for an EU-wide legally binding decision.

Contact our press officers

Monika Benstetter or Martin Harvey

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu