07 March 2013
EMA/133894/2014

PRAC re-examines diacerein and recommends that it remain available with restrictions

Restrictions intended to limit risks of severe diarrhoea and effects on the liver

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has re-examined diacerein-containing medicines and is recommending that they remain available but with restrictions to manage the risks of severe diarrhoea and effects on the liver.

Due to the risks associated with severe diarrhoea, diacerein is no longer recommended in patients aged 65 years and above. It is also advised that patients start treatment on half the normal dose (i.e. 50 mg daily instead of 100 mg) and should stop taking diacerein if diarrhoea occurs.

In addition, diacerein-containing medicines must now not be used in any patient with liver disease or a history of liver disease, and doctors should be monitoring their patients for early signs of liver problems.

The PRAC further recommends that diacerein should only be started by doctors experienced in treating osteoarthritis. Doctors should note that, based on available data, the use of diacerein is to be limited to treating symptoms of osteoarthritis affecting the hip or knee.

These recommendations are the outcome of a re-examination of the PRAC's November 2013 opinion, which recommended the suspension of diacerein due to concerns over the risks of severe diarrhoea and liver effects. During the re-examination, the Committee considered new proposals to manage these risks and is now satisfied that the proposed restrictions will be sufficient to ensure that diacerein's benefits outweigh its risks. The official product information for diacerein-containing medicines is to be updated with the new recommendations.

The PRAC's review of diacerein was started 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. The PRAC's final recommendations will be sent to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) for consideration at its meeting on 17-19 March 2014.

Further details on the recommendations for healthcare professionals and patients will be made public after the CMDh meeting.

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 PRAC made its initial recommendations in November 2013 and within 15 days of the recommendations some marketing-authorisation holders for diacerein exercised their right to request a re-examination. This re-examination has now concluded and the PRAC's final recommendations will be forwarded to the 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