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Review of diacerein started

The European Medicines Agency (EMA) has started a review of diacerein-containing medicines used to treat the symptoms of osteoarthritis and other joint diseases, such as joint pain and stiffness.

This follows a review by the French medicines agency, which concluded in July 2012 that the benefits of diacerein did not outweigh its risks in the symptomatic treatment of osteoarthritis of the hip and knee. The French review was carried out as part of an exercise to re-evaluate nationally authorised products that had been authorised in France before 2005.

In its conclusions, the French agency cited safety concerns (very frequent digestive disorders, some serious cases of liver disorders and skin reactions) and also evidence from clinical trials and the scientific literature suggesting that the effectiveness of diacerein in osteoarthritis was weak.

The European Medicines Agency will now review the available data on the benefits and risks of diacerein and issue an opinion on the marketing authorisations of diacerein-containing medicines across the EU.

More about the medicine

Diacerin is an anti-inflammatory medicine that works by blocking the actions of interleukin-1, a protein involved in the process of inflammation, which plays a role in the development of osteoarthritis and other joint diseases.

Diacerin-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 has been initiated at the request of the French medicines agency under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As diacerein-containing medicines are all authorised nationally, the PRAC

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recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which is a regulatory body that represents national medicines regulatory authorities of the EU Member States. This will result in harmonised measures to be implemented in all Member States.