31/01/2019
EMA/790726/2018
EMEA/H/A-29(4)/1474

EMA recommends authorisation of Diotop (diclofenac / omeprazole capsules) in the EU

EMA completes review following disagreement among EU Member States

On 15 November 2018, the European Medicines Agency completed a review of Diotop following a disagreement among EU Member States regarding its authorisation. The Agency concluded that the benefits of Diotop outweigh its risks, and the marketing authorisation granted in the United Kingdom can be recognised in other Member States of the EU where the company has applied for a marketing authorisation.

What is Diotop?

Diotop is a medicine used to relieve symptoms such as swelling and pain caused by the joint disorders rheumatoid arthritis, osteoarthritis or ankylosing spondylitis. Diotop is used in adult patients who are at risk of developing stomach ulcers and whose disease is already controlled by diclofenac and omeprazole, the two active substances in Diotop, taken separately.

The two active substances in Diotop have different effects. Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID) used for the relief of pain and inflammation in a wide range of conditions. Omeprazole is a widely-used treatment for indigestion and acid reflux that acts by reducing the amount of acid the stomach makes. Both diclofenac and omeprazole have been authorised in the EU for many years.

Why was Diotop reviewed?

Temmler Pharma GmbH requested that the marketing authorisation for Diotop granted by the UK and Austria in 2016 be recognised in Germany (the 'concerned Member State').

However, the Member States were not able to reach an agreement and the UK medicines regulatory agency referred the matter to EMA for arbitration on 28 September 2018.

The grounds for the referral were concerns raised by Germany that the data provided by the company were not enough to demonstrate the safety and effectiveness of Diotop.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

What is the outcome of the review?

The company submitted data from the published literature on the use of several NSAIDs (including diclofenac at the dose of 50 to 150 mg a day) and omeprazole in combination. The Agency considered that, although the particular combination in Diotop (diclofenac 75 mg / omeprazole 20 mg) has never been tested in any published study, the data from studies of higher doses of diclofenac or other NSAIDs taken with omeprazole are enough to support the use of the specific combination in Diotop.

The Agency therefore concluded that the benefits of Diotop outweigh its risks, and therefore the marketing authorisation for Diotop should be granted in Germany.

More about the procedure

The review of Diotop was initiated at the request of the United Kingdom, under Article 29(4) of Directive 2001/83/EC.

The review was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use.

The European Commission issued an EU-wide legally binding decision on the marketing authorisation of Diotop on 31/01/2019.