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Questions and answers on diclofenac epolamine 50 mg tablets

Outcome of a procedure under Article 29(4) of Directive 2001/83/EC

On 21 July 2016, the European Medicines Agency completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine diclofenac epolamine (50 mg tablets). The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of this product do not outweigh its risks, and the marketing authorisation cannot be granted in the United Kingdom (UK) or in the following Member States of the EU: Czech Republic, France and Slovakia.

What is diclofenac epolamine (50 mg tablets)?

The active substance in this medicine, diclofenac, is used for relief of pain and inflammation. Diclofenac is a 'non-steroidal anti-inflammatory drug' (NSAID) which reduces the body's production of substances called prostaglandins. Since some prostaglandins are involved in causing pain and inflammation at sites of injury or damage in the body, reduced prostaglandin production reduces pain and inflammation.

Diclofenac epolamine (50 mg tablets) is a generic medicine based on a 'reference medicine', Flector, which is authorised in France. The medicine was to be marketed as Diclofenac.

Why is diclofenac epolamine (50 mg tablets) reviewed?

Altergon Italia srl submitted diclofenac epolamine (50 mg tablets) to the UK medicines regulatory agency for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance the UK) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', in this instance Czech Republic, France and Slovakia).

However, the Member States were not able to reach an agreement and the UK medicines regulatory agency referred the matter to the CHMP for arbitration on 5 February 2016.

Because diclofenac epolamine (50 mg tablets) is a generic medicine, a study has been carried out to show that it is bioequivalent to the reference medicine, Flector, which is available as diclofenac

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epolamine granules to make a solution for drinking. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

The grounds for the referral were that the study performed had only shown the medicine was bioequivalent to the reference medicine when taken on an empty stomach. The French and Slovakian medicines regulatory agencies considered that a bioequivalence study of the medicine taken with food was also required because it is recommended to be preferably taken with food.

What are the conclusions of the CHMP?

Based on the evaluation of currently available data and the scientific discussion within the Committee, the CHMP concluded that bioequivalence to the reference medicine when taken with food has not been shown. A review of scientific literature showed variable reductions in the uptake of different forms of diclofenac when taken with food. The CHMP therefore considered that the study of the medicine taken on an empty stomach only was not sufficient to show that this product is as effective as the reference medicine. This is because it is recommended that this product is preferably taken with food, and food can have a big effect on the way the medicine is taken up into the body. The CHMP concluded that the benefits of these diclofenac epolamine 50 mg tablets do not outweigh their risks and recommended that marketing authorisation should not be granted in the UK or in the concerned Member States.

The European Commission issued a decision on this opinion on 22-09-2016.