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EMA recommends authorisation of Flurbiprofen Geiser (flurbiprofen, 8.75 mg, oromucosal spray) in the EU

On 17 October 2019, the European Medicines Agency completed a review of Flurbiprofen Geiser following a disagreement among EU Member States regarding its authorisation. The Agency concluded that the benefits of Flurbiprofen Geiser outweigh its risks, and the marketing authorisation can be granted in Spain and in other Member States of the EU where the company has applied for a marketing authorisation: Czech Republic, the Netherlands, Portugal and Slovakia.

What is Flurbiprofen Geiser?

Flurbiprofen Geiser is a medicine used for the short-term relief of symptoms of sore throat. Flurbiprofen Geiser contains the active substance flurbiprofen, 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 in the body, reducing prostaglandin production reduces pain and inflammation.

Flurbiprofen Geiser was developed as a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance. However, the reference medicine, Strefen Direct, has a different concentration to Flurbiprofen Geiser. In addition Flurbiprofen Geiser has a different flavour and contains smaller amounts of substances called cyclodextrins, which help to stabilise the solution.

Why was Flurbiprofen Geiser reviewed?

Geiser Pharma S.L. submitted Flurbiprofen Geiser to the Spanish medicines agency for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Spain) 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, the Netherlands, Portugal and Slovakia) where the company has applied for a marketing authorisation.

However, the Member States were not able to reach an agreement and the Spanish medicines agency referred the matter to EMA for arbitration on 10 June 2019.

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The grounds for the referral were concerns that the laboratory data submitted were not enough to show that Flurbiprofen Geiser is equally as effective as Strefen Direct. Because there is a small difference in concentration between the two medicines, it was considered that data from a clinical trial in healthy volunteers would be needed to determine whether they have the same effect. The medicines also have different flavours and different amounts of cyclodextrins and this could affect how the active substance is taken up into the body.

What is the outcome of the review?

Having reviewed the available data, EMA considered that differences between Flurbiprofen Geiser and Strefen Direct are minor and do not affect the amount of active substance that is released in the mouth and into the bloodstream. Published data show that differences of this size in concentration of the active substance, flavour and amount of cyclodextrins do not affect how the medicine works. This is supported by data showing that even flurbiprofen medicines taken by mouth in very different forms, such as lozenges, granules and spray, behave the same way in the body.

Based on evaluation of the currently available data, the Agency concluded that the benefits of Flurbiprofen Geiser outweigh its risks, and therefore the marketing authorisation for Flurbiprofen Geiser should be granted in all concerned Member States.

More about the procedure

The review of Flurbiprofen Geiser was initiated on 27 June 2019 at the request of Spain, 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 Flurbiprofen Geiser on 16/12/2019.