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Change not granted to the marketing authorisation for Basiron AC (benzoyl peroxide 5% and 10% gel) in the EU

On 28 March 2019, the European Medicines Agency completed a review of Basiron AC (benzoyl peroxide) following a disagreement among EU Member States regarding a change in the marketing authorisation of this medicine. In particular, the Agency was requested to make a recommendation on a change in the medicine's formulation that would allow for greater stability in warmer countries. As the Agency could not conclude whether the change would impact on the effectiveness and safety of the medicinal product, the change in formulation cannot be granted.

What is Basiron AC?

Basiron AC is a medicine used to treat acne. It is available as a gel to be applied on the affected skin.

The medicine contains the active substance benzoyl peroxide, which kills certain bacteria that are associated with acne and has skin-peeling effects.

Basiron AC is authorised in Austria, Belgium, Denmark, Ireland, Italy, Finland, France, Germany, Luxemburg, the Netherlands, Norway, Portugal, Spain and Sweden. The company that markets the medicine is Galderma Nordic AB.

Why was Basiron AC reviewed?

Basiron AC has been authorised in the EU via national procedures.

In December 2017, Galderma Nordic AB submitted an application to the Swedish medicines agency, MPA, to change the formulation of the medicine by replacing the gelling agent Carbomer 940 with Simulgel 600 PHA. The change aimed to improve the stability of the gel to allow for a longer shelf-life in warmer countries.

The company wanted this change to be recognised in all the other Member States where the medicine is authorised.

However, the Member States were not able to reach an agreement and the Dutch medicines agency referred the matter to EMA for arbitration on 26 October 2018.

The grounds for the referral were concerns that the data provided by the company were insufficient to conclude that the change in formulation would not impact the effectiveness and safety of the medicine.

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The company had provided data from laboratory studies that compared the skin absorption and penetration with the old and new formulation. In addition, the company provided data from clinical studies with another medicine, Epiduo (benzoyl peroxide and adapalene), containing the gelling agent Simulgel 600 PHA. However, no clinical studies were performed with the new formulation of Basiron AC.

What is the outcome of the review?

The Agency evaluated the currently available data but could not conclude whether the change in formulation would impact the effectiveness and safety of the medicine on the basis of the data provided. As a result, the change in formulation cannot be approved in all concerned Member States.

More about the procedure

The review of Basiron AC was initiated on 15 November 2018 at the request of the Netherlands, under Article 13 of Regulation (EC) No 1234/2008.

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

A European Commission decision valid throughout the EU was issued on 4 July 2019.