26 March 2020
EMA/CHMP/117524/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Jorveza

budesonide

On 26 March 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Jorveza. The marketing authorisation holder for this medicinal product is Dr. Falk Pharma GmbH.

The CHMP adopted a change to the duration of treatment allowing the use of Jorveza as maintenance therapy for eosinophilic esophagitis in adults (older than 18 years of age) with a new strength (0.5 mg orodispersible tablet).

The recommendation for maintenance therapy is as follows:

> The recommended daily dose is 1 mg budesonide as one 0.5-mg-tablet in the morning and one 0.5-mg-tablet in the evening or 2 mg budesonide as one 1-mg-tablet in the morning and one 1-mg-tablet in the evening, depending on the individual clinical requirement of the patient.
>
> A maintenance dose of 1 mg budesonide twice daily is recommended for patients with a long standing disease history and/or high extent of esophageal inflammation in their acute disease state.
>
> The duration of maintenance therapy is determined by the treating physician.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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