9 November 2017
EMA/CHMP/733678/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Jorveza

budesonide

On 9 November 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Jorveza, intended for the treatment of eosinophilic esophagitis. Jorveza, which was designated as an orphan medicinal product on 05 August 2013, was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Dr. Falk Pharma GmbH.

Jorveza will be available as 1-mg orodispersible tablets. The active substance of Jorveza is budesonide, a locally acting corticosteroid which works primarily via binding to the glucocorticoid receptor (ATC code: A07EA06). In the treatment of eosinophilic esophagitis, budesonide inhibits antigen-stimulated secretion of many pro-inflammatory signal molecules such as thymic stromal lymphopoeitin, interleukin-13 and eotaxin-3 in the esophageal epithelium, resulting in a significant reduction of the esophageal eosinophilic inflammatory infiltrate.

The benefits with Jorveza are its ability to reduce eosinophil infiltrations into the oesophageal mucosa and reduce relevant symptoms of the disease such as dysphagia and pain during swallowing.

The most common side effects seen in studies were fungal infections both of the oesophagus and the oral cavity (including the pharynx), which occur in about 30% of the population treated. However these infections did not lead to treatment discontinuation, were mostly asymptomatic, and, in most cases, were treated successfully with standard antifungal treatments. Further common side effects observed were headache, nausea, dyspepsia, interaction with CYP3A4 inhibitors, gastroesophageal reflux disease, decreased cortisol levels and lip oedema.

The full indication is: "Jorveza is indicated for the treatment of eosinophilic esophagitis (EoE) in adults (older than 18 years of age)."

It is proposed that treatment with Jorveza is initiated by physicians experienced in the diagnosis and treatment of eosinophilic esophagitis.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made

[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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

available in all official European Union languages after the marketing authorisation has been granted by the European Commission.