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EPAR summary for the public

Jorveza

budesonide

This is a summary of the European public assessment report (EPAR) for Jorveza. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Jorveza.

For practical information about using Jorveza, patients should read the package leaflet or contact their doctor or pharmacist.

What is Jorveza and what is it used for?

Jorveza is a medicine used to treat adults with eosinophilic oesophagitis. Eosinophilic oesophagitis is inflammation of the oesophagus (the food-pipe that leads from the mouth to the stomach), which causes symptoms including dysphagia (difficulty swallowing) and obstruction of the oesophagus. It is caused by a large build-up of white blood cells called eosinophils in the lining of the oesophagus. Jorveza contains the active substance budesonide.

Because the number of patients with eosinophilic oesophagitis is low, the disease is considered 'rare', and Jorveza was designated an 'orphan medicine' (a medicine used in rare diseases) on 5 August 2013.

How is Jorveza used?

Jorveza can only be obtained with a prescription and treatment should be started by a doctor experienced with diagnosing and treating eosinophilic oesophagitis.

Jorveza is available as orodispersible tablets (1 mg). The tablet is placed on the tongue and pressed against the roof of the mouth for around two minutes until it dissolves. During this time the patient should steadily swallow the saliva with the dissolved medicine. Tablets must not be chewed or

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

swallowed whole. The recommended dose is one tablet twice a day. Treatment is continued for 6 weeks, but may be extended for up to another 6 weeks if needed.

For further information, see the package leaflet.

How does Jorveza work?

The active substance in Jorveza, budesonide, is a corticosteroid medicine. Corticosteroids help reduce inflammation by attaching to receptors of immune cells and reducing the release of substances that are involved in the inflammation process.

After Jorveza dissolves in the mouth, the saliva carries it to the oesophagus where it reduces the inflammation and relieves the symptoms of eosinophilic oesophagitis.

What benefits of Jorveza have been shown in studies?

Jorveza was shown to be effective in one main study involving 88 adults with eosinophilic oesophagitis. The main measure of effectiveness was the level of eosinophils in the oesophagus and improvement in symptoms. Jorveza was compared with placebo (a dummy treatment). After 6 weeks, around 58% of the patients taking Jorveza (34 out of 59 patients) had reduced eosinophils and no symptoms or only minimal symptoms, whereas none of the 29 patients taking placebo had these effects.

What are the risks associated with Jorveza?

The most common side effects with Jorveza (which may affect up to 3 in 10 people) are fungal infections in the mouth, pharynx (throat) and oesophagus.

For the full list of all side effects and restrictions with Jorveza, see the package leaflet.

Why is Jorveza approved?

Jorveza benefits patients with eosinophilic oesophagitis by improving the symptoms of the disease and reducing the excess of eosinophils. These patients often do not have other treatment options. Side effects with Jorveza are mainly the same as those of other similar medicines. The European Medicines Agency decided that Jorveza's benefits are greater than its risks and recommended that it be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Jorveza?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Jorveza have been included in the summary of product characteristics and the package leaflet.

Other information about Jorveza

The European Commission granted a marketing authorisation valid throughout the European Union for Jorveza on 8 January 2018.

The full EPAR for Jorveza can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Jorveza, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Jorveza can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 01-2018.