EMA/170647/2020
EMEA/H/C/004655

Jorveza (*budesonide*)

An overview of Jorveza and why it is authorised in the EU

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 passage that leads from the mouth to the stomach), which causes symptoms such as dysphagia (difficulty swallowing) and blockage of the oesophagus. It is caused by a large build-up of white blood cells called eosinophils in the lining of the oesophagus.

Eosinophilic oesophagitis is rare, and Jorveza was designated an 'orphan medicine' (a medicine used in rare diseases) on 5 August 2013. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu3131181.

Jorveza contains the active substance budesonide.

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 (0.5 mg and 1 mg). The tablet is placed on the tongue and pressed against the roof of the mouth for at least 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 swallowed whole.

The recommended dose to bring symptoms under control is one 1-mg tablet twice a day for 6 to 12 weeks. To keep the condition under control, treatment with Jorveza can be continued with one 0.5-mg or 1-mg tablet twice a day, depending on how long the patient has had the condition and how severe it is. The doctor will decide how long the treatment should last.

For more information about using Jorveza, see the package leaflet or contact your doctor or pharmacist.

How does Jorveza work?

The active substance in Jorveza, budesonide, is a corticosteroid. Corticosteroids attach to targets (receptors) on immune cells and reduce the release of substances that lead to inflammation.

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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 effective in two main studies involving 292 adults with eosinophilic oesophagitis.

In the first study involving 88 patients with active eosinophilic oesophagitis, treatment with 1 mg of Jorveza twice a day was compared with placebo (a dummy treatment). The main measure of effectiveness was the level of eosinophils in the oesophagus and improvement in symptoms. After 6 weeks, around 58% of the patients taking Jorveza had reduced eosinophil levels and no symptoms or only minimal symptoms, whereas none of the patients taking placebo had these effects.

In the second study, involving 204 patients whose symptoms of eosinophilic oesophagitis were under control, treatment with 0.5 mg or 1 mg Jorveza twice a day was compared with placebo. After 48 weeks, symptoms were satisfactorily controlled in around 74% of patients taking 0.5 mg Jorveza twice a day and 75% of those taking 1 mg twice a day, compared with 4% in those receiving placebo.

What are the risks associated with Jorveza?

The most common side effects with Jorveza (which may affect more than 1 in 10 people) are fungal infections in the mouth, pharynx (throat) and oesophagus.

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

Why is Jorveza authorised in the EU?

The European Medicines Agency decided that Jorveza's benefits are greater than its risks and it can be authorised for use in the EU.

Patients with eosinophilic oesophagitis often do not have other treatment options. The Agency concluded that Jorveza improves the symptoms of eosinophilic oesophagitis and reduces the excess of eosinophils. Jorveza is also effective in preventing recurrent episodes of the disease. Side effects of Jorveza, which mainly affect the mouth and throat, are manageable.

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.

As for all medicines, data on the use of Jorveza are continuously monitored. Side effects reported with Jorveza are carefully evaluated and any necessary action taken to protect patients.

Other information about Jorveza

Jorveza received a marketing authorisation valid throughout the EU on 8 January 2018.

Further information on Jorveza can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/jorveza.

This overview was last updated in 03-2020.