Information for primary care — Budesonide orodispersible tablets (Jorveza®)

RAG Status – Green +

Background/Summary information

Eosinophilic oesophagitis (EoE) is characterised by a marked accumulation of eosinophils in the oesophageal mucosa. Severe squamous epithelial hyperplasia generally occurs, resulting in complications such as oesophageal strictures and a narrow oesophagus. Symptoms include heartburn, chest pain, dysphagia, pain on swallowing, vomiting, food impaction, and feeding intolerance).

EoE affects all age groups, but more commonly men aged 30 – 50. In 2017, it was estimated that 22,000 of the adult UK population were affected. It is not known why some people suffer with EoE, but it is thought there may be a genetic link. Around half of people with EoE also have other allergic conditions such as allergic rhinitis, eczema or asthma.

Budesonide inhibits antigen-stimulated secretion of many pro-inflammatory signal molecules in the oesophageal epithelium, which results in a reduction of the oesophageal eosinophilic inflammatory infiltrate.

Related NICE guidance

None, but a Technology Appraisal is due July 2020

See manufacturer's SPC (Jorveza®) for full prescribing information
http://www.medicines.org.uk/emc/product/9446

Licensed indication

The treatment of eosinophilic esophagitis (EoE) in adults (older than 18 years of age).

Dosage and administration

Usual dose:
The recommended dose is one 1mg-tablet in the morning and evening for a 12 week course.

It should be allowed to dissolve on the tongue which usually takes about two minutes. The dissolved material should be swallowed with saliva little by little while the orodispersible tablet disintegrates, The orodispersible tablet should not be taken with liquid or food.

Key points for safe use:

- *Renal impairment*: Although budesonide is not renally excreted, no data in impairment is available. Patients with mild to moderate impairment may be treated with caution with no change in dose. Jorveza® is not recommended in severe renal impairment.
- *Hepatic impairment*: May affect the elimination of budesonide causing higher systemic exposure. No data is available so caution in patients with hepatic impairment.
- *Pregnancy and lactation*: The BNF states that the benefit of treatment with corticosteroids during pregnancy and breast feeding outweighs the risk. Pregnant women taking systemic corticosteroids with fluid retention should be monitored closely.
- Each orodispersible tablet contains 26 mg sodium.

GP and specialist responsibilities

- The GP will provide prescriptions for the patient in line with the instructions given by the gastroenterologist in secondary care.
- The gastroenterologist will provide advice and answer queries on the use of this drug and can be contacted on 0191 565 6256.

Contraindications
Hypersensitivity to the active substance or to any of the excipients: disodium hydrogen citrate, docusate sodium, macrogol 6000, magnesium stearate, mannitol, anhydrous monosodium citrate, povidone K25, sodium hydrogen carbonate and sucralose
Cautions
Patients are more susceptible to infection and symptoms can be atypical or masked. Chickenpox, herpes zoster and measles can have a more serious course in patients treated with glucocorticoids and particular care should be taken to avoid exposure. Systemic corticosteroids should be used with caution in heart failure, recent myocardial infarction, hypertension, diabetes mellitus, epilepsy, glaucoma, hypothyroidism, osteoporosis, peptic ulceration, psychoses or severe affective disorders. Glucocorticoids may cause suppression of the hypothalamic–pituitary–adrenal (HPA) axis and reduce the stress response. When patients are subject to surgery or other stresses, supplementary systemic treatment may be needed.
Side effects
Headache, oral and/or oropharyngeal candidiasis, hypertension, upper abdominal pain, gastroesophageal reflux disease, lip oedema, nausea, oral paraesthesia, blood cortisol levels decreased.
Drug interactions
Co-treatment with potent CYP3A inhibitors such as ketoconazole, ritonavir, itraconazole, clarithromycin, cobicistat and grapefruit juice may cause a marked increase of the plasma concentration of budesonide and potentiate adverse reactions. Corticosteroids can cause hypokalaemia which may affect digoxin; hypokalaemia may be enhanced by concomitant diuretics.
Monitoring
No monitoring is required and the patient will be reviewed by the specialist at 4-6 months.
Cost
£323.00 (excluding VAT) for 90 tablets