

FOOD BOLUS OBSTRUCTION:

WHO SEES THE PATIENT WITH FBO?

Approximately half of patients with a food bolus obstruction presenting as an emergency...



↓ Ear, Nose & Throat

...are admitted under ENT^{1,2}



HES database, England 2008-2019, 10,417 adults presenting to A&E with an FBO (ICD-10 code: T18.1); 52% admitted under ENT¹

Often the area where FBO patients feel discomfort does not correlate with the site of obstruction^{3,4}

Unless patients are struggling to breathe, most food boluses stick in the body of the oesophagus⁵

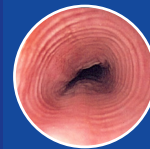
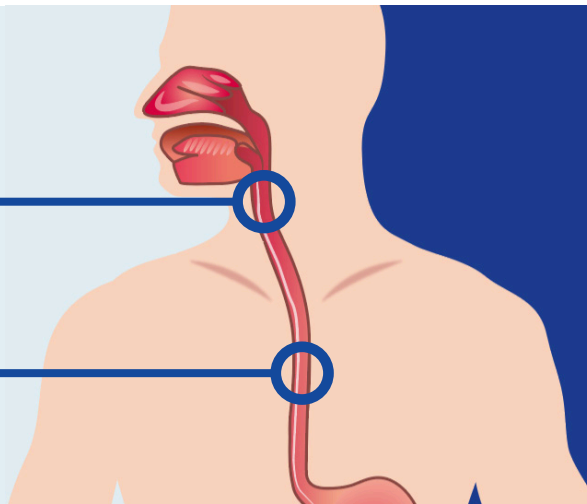
Timing of regurgitation after swallowing liquid is suggestive of the obstruction location³

immediate coughing and choking

obstruction at the level of the cricopharynx

delayed regurgitation

obstruction lower down the oesophagus



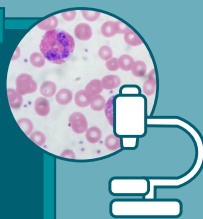
The most likely cause of FBO is eosinophilic oesophagitis⁵

EoE is a chronic, inflammatory condition in which eosinophils infiltrate the oesophageal epithelium⁷

The condition can lead to fibrostenotic disease⁶

While symptoms such as swallowing difficulties point to EoE, it takes histology to confirm the diagnosis⁶

EoE:
≥15 eos per hpf
or
≥15 eos/
0.3 mm²



The HES data show 70% of FBO patients admitted under ENT underwent endoscopy, but only 12% had biopsies to exclude EOE¹

Recent British Society of Gastroenterology guidelines recommend:⁶

- Considering EoE in all adult patients with an FBO
- Making an urgent referral to gastroenterology for a therapeutic OGD
- Taking ≥6 biopsies from different anatomical sites in the oesophagus at the index endoscopy

10
years +

Roughly one-third of EoE patients wait over 10 years for a diagnosis; some 40% of these patients will have developed oesophageal strictures waiting to be diagnosed^{8,9}

Image courtesy of Professor Stephen Attwood

“ FBO “...presents a unique opportunity to diagnose, treat and establish care for patients with EoE”¹⁰ ”

Complex patient journeys can delay diagnosis and access to treatment¹¹

Unless the airway is impaired, FBO is best managed under general medicine/gastroenterology¹¹

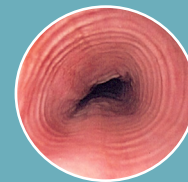
EoE can turn any meal into an emergency, with chronic oesophageal inflammation and progressive fibrosis obstructing the passage of food¹²

Jorveza (orodispersible budesonide) was specifically designed to treat EoE.¹³ The only oral medicine with European regulatory approval for EoE, Jorveza treats both the symptoms of EoE and its defining histology¹⁴

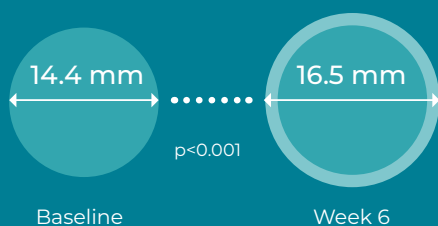


At **6** weeks
Within weeks, oesophageal distensibility improved in 94% of Jorveza patients¹⁶

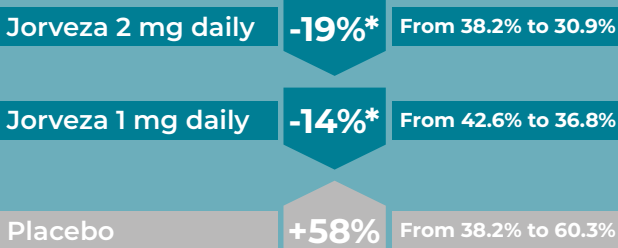
At **48** weeks
Prolonged treatment with Jorveza can delay and even revert fibrotic remodelling¹⁵



Mean oesophageal diameter on Jorveza



Patients with fixed rings (% change from baseline at week 48)¹⁵



*p < 0.01 vs placebo

Jorveza is highly effective at both achieving and maintaining remission, and reducing the fibrotic complications of EoE^{14,15}

Discharge of FBO patients without a gastroenterology consultation may result in a missed underlying diagnosis¹⁷

A MISSED EoE DIAGNOSIS IS A MISSED OPPORTUNITY TO TREAT

BUDESONIDE
Jorveza[®]
ORODISPERSIBLE TABLETS

Prescribing Information (refer to full SmPC before prescribing).

Presentations: Jorveza 1mg and 0.5mg orodispersible tablets containing 1mg or 0.5mg of budesonide. **Indications:** treatment of eosinophilic esophagitis (EoE) in adults (older than 18 years of age). **Dosage:** Induction of remission: one 1mg tablet taken twice daily (morning and evening) after a meal and immediately after removal of the tablet from the blister pack. Usual duration of induction treatment is 6 weeks. Extend up to 12 weeks for non-responding patients. **Maintenance of remission:** 0.5mg twice daily or 1mg twice daily depending on clinical need. A maintenance dose of 1mg twice daily is recommended for patients with long-standing disease history and/or high extent of oesophageal inflammation in the acute disease state. Duration of maintenance treatment - to be determined by the treating physician. **Administration:** tablet is placed on tip of tongue and pressed to top of mouth then swallowed slowly without liquid or food and without chewing or swallowing undissolved. May take 2 to 20 minutes to disintegrate and swallow completely. Wait at least 30 minutes before eating, drinking or performing oral hygiene. **Contraindications:** hypersensitivity to budesonide or any ingredient of the tablets. **Warnings/precautions:** Infections - suppression of inflammatory response and immune function increases susceptibility to infections and their severity which can be atypical or masked. Oral, oropharyngeal and oesophageal candida infections occur at high frequency. Treat symptoms with topical or systemic anti-fungals. Jorveza treatment can continue. Chickenpox, herpes zoster and measles - can be more serious in patients treated with glucocorticosteroids. Check vaccination status. Avoid exposure. **Vaccines** - avoid co-administration of live vaccines and glucocorticosteroids. The antibody response to other vaccines may be diminished. **Special populations** - monitor patients with tuberculosis, hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma, cataract, family history of diabetes, family history of glaucoma. **Systemic effects of glucocorticosteroids** - may occur, depending on duration of treatment, concomitant and previous glucocorticosteroid treatment and individual sensitivity. Patients with reduced liver function - an increased systemic availability of budesonide may be expected, with increased risk of adverse reactions. Patients with hepatic impairment should not be treated. Not recommended for use in patients with severe renal impairment. **Angioedema** - treatment should be stopped if signs of angioedema are observed. **Visual disturbance** - patients with blurred vision or other visual disturbances should be considered for referral to an ophthalmologist. Causes may include cataract, glaucoma or central serous chorioretinopathy resulting from corticosteroid use. **Others** - glucocorticosteroids 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 glucocorticosteroid treatment is therefore recommended. Concomitant treatment with ketoconazole or other CYP3A4 inhibitors should be

avoided. **Serological testing** - adrenal function may be suppressed by budesonide so an ACTH stimulation test for diagnosing pituitary insufficiency might show false (low) results. **Sodium** - contains 52 mg of sodium per daily dose. **Interactions:** CYP3A4 inhibitors - concomitant treatment with ketoconazole or other potent CYP3A4 inhibitors including grapefruit juice should be avoided to reduce the risk of systemic side effects unless the benefit outweighs the risk. Such treatment should be monitored. **Oestrogens, oral contraceptives** - may elevate plasma concentrations and enhance effects of glucocorticosteroids. Concomitant intake of low-dose combination oral contraceptives has not shown this effect. **Cardiac glycosides** - action of glycoside can be potentiated by potassium deficiency - a potential and known adverse reaction of glucocorticosteroids. **Saluretics** - potassium excretion can be enhanced and hypokalaemia aggravated. **Use in pregnancy:** should be avoided unless there are compelling reasons for therapy. **Breast-feeding** - budesonide is excreted in human milk. The benefit of breast feeding for the child and the benefit of therapy for the woman should be assessed. **Fertility** - there are no data on the effect of budesonide on human fertility. **Undesirable effects:** fungal infections in the mouth, pharynx and the oesophagus were the most frequently observed adverse reactions in clinical studies. Long term treatment did not increase the rate. **Adverse reactions and frequencies:** **Very common:** esophageal candidiasis, oral and/or oropharyngeal candidiasis. **Common:** sleep disorder, headache, dysgeusia, dry eyes, gastroesophageal reflux disease, nausea, oral paraesthesia, dyspepsia, upper abdominal pain, dry mouth, glossodynia, tongue disorder, oral herpes, fatigue, blood cortisol decreased. **Uncommon:** nasopharyngitis, pharyngitis, angioedema, anxiety, agitation, dizziness, hypertension, cough, dry throat, oropharyngeal pain, abdominal pain, abdominal distension, dysphagia, erosive gastritis, gastric ulcer, lip edema, gingival pain, rash, urticaria, sensation of foreign body, osteocalcin decreased, weight increased. **Other (class) effects with unknown frequency that may occur:** increased risk of infection, Cushing's syndrome, adrenal suppression, growth retardation in children, hypokalaemia, hyperglycaemia, depression, irritability, euphoria, psychomotor hyperactivity, aggression, pseudotumor cerebri including papilloedema in adolescents, glaucoma, cataract (including subcapsular cataract), blurred vision, central serous chorioretinopathy (CSCR), increased risk of thrombosis, vasculitis (withdrawal syndrome after long-term therapy), duodenal ulcers, pancreatitis, constipation, allergic exanthema, petechiae, delayed wound healing, contact dermatitis, ecchymosis, muscle and joint pain, muscle weakness and twitching, osteoporosis, osteonecrosis, malaise. **Legal category:** POM. **Cost:** 1mg - pack of 90 - £323; 0.5mg - pack of 60 - £214.80. Not currently available in Ireland. **Product licence holder:** Dr. Falk Pharma GmbH. **Product licence number:** 1E/N/1: 1mg: EU/1/17/1254/004, 0.5mg: EU/1/17/1254/008. GB: 1mg: PLGB08637/0030; 0.5mg: PLGB08637/0032.

Date of preparation: February 2023.
Further information is available on request.

Adverse events should be reported. Visit <https://yellowcard.mhra.gov.uk/>. Adverse events should also be reported to Dr Falk Pharma UK Ltd. at PV@drfalkpharma.co.uk

References:

- Umar N *et al.* Gut 2023; 72: A130-A131.
- Ntuli Y *et al.* Frontline Gastroenterology 2020; 11: 11-15.
- Stubington TJ, Kamani T. Eur Arch Otorhinolaryngol 2021; 278(10): 3613-23.
- Pollard WS, Bloomfield AL. J Clin Invest 1931; 10(3): 435-52.
- Becq A, Camus M, Dray X. Frontline Gastroenterol 2020; 12(7): 664-70.
- Dhar A *et al.* Gut 2022; 71(8):1459-87.
- Oliva S, Dellon ES. Dig Liver Dis 2021; 53(11): 1476-8.
- Murray FR *et al.* Am J Gastroenterol 2022; 117: 1772-9.
- Hilas O. US Pharm 2022; 47(12): 14.
- Donohue S *et al.* Am J Gastroenterol 2019; 114: S269.8.
- Narghees N, Peedikata T. Br J Surg 2021; 108(Suppl. 2): Abs 995.
- Attwood S, Epstein J. Frontline Gastroenterol 2020; 12(7): 644-9.
- Miehke S *et al.* Therap Adv Gastroenterol 2020; 13: 1756284820927282.
- Lucendo AJ *et al.* Gastroenterology 2019; 157: 74-86.
- Biedermann L *et al.* United Eur Gastroenterol J 2019; 7: 55.
- Lucendo AJ *et al.* Gastroenterology 2021; 160(6): S-247.
- Fulforth JM *et al.* Emerg Med Australas 2019; 31(5): 745-9.

A&E: accident & emergency
ENT: ear, nose & throat
EoE: eosinophilic oesophagitis
eos: eosinophils
FBO: food bolus obstruction
HES: Hospital Episode Statistics
hpf: high power field
OGD: oesophagogastroduodenoscopy

UK-2300144
Date of preparation: December 2023

Dr Falk Pharma UK Ltd, Unit K, Bourne End Business Park, Cores End Rd, Bourne End, SL8 5AS.
Registered in England No: 2307698