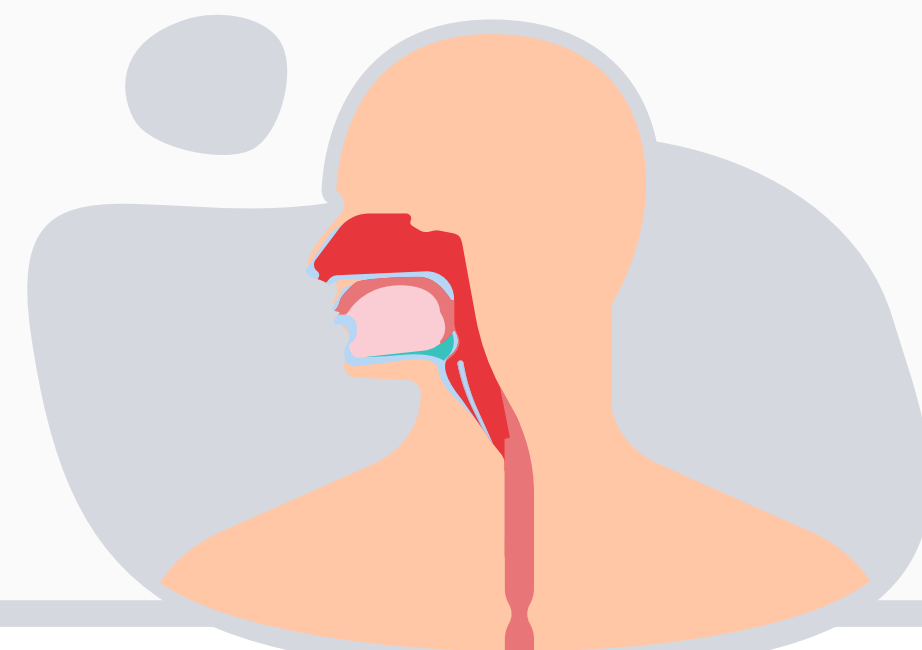


Eosinophilic oesophagitis (EoE)

What is eosinophilic oesophagitis?

Eosinophilic oesophagitis (EoE) is a chronic inflammatory condition of the oesophagus, in which the body overproduces a type of white blood cell called eosinophils, leading to inflammation in the oesophagus.^{1,2}



The burden of EoE



Rarely detected 30 years ago, EoE is becoming common. Pooled estimates of global annual incidence and prevalence are **5.3 and 40/100,000 population**, respectively.^{3,4}

Based on an annual estimated incidence of **5.3 per 100,000 population**,³ the UK has an incidence of about **3,551 cases per year**.⁵

Symptoms of EoE can be unpleasant and socially embarrassing and can have a significant impact on quality of life.²



Worries about choking episodes⁶

Social embarrassment and distress⁶

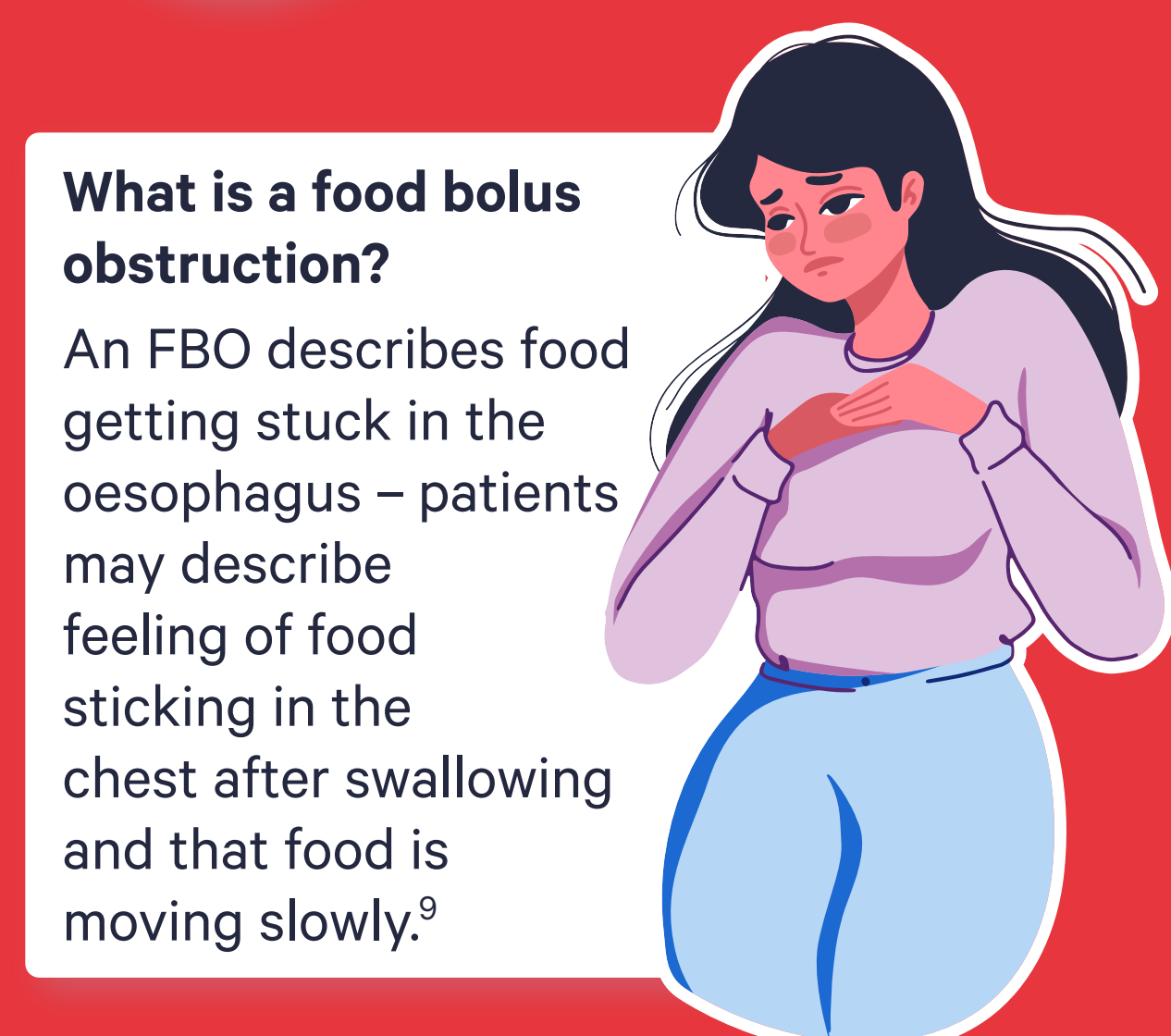
Modified social behaviour and adapted eating habits⁷

Anxiety and depression⁶

How do people present with EoE?



Once initially regarded as a disease of younger people, EoE is now known to present at any age. The incidence rises during adolescence and peaks in early adulthood.⁸ In about one third of people, the first episode of EoE is an acute food bolus obstruction (FBO),¹ requiring emergency hospital attendance.



What is a food bolus obstruction?

An FBO describes food getting stuck in the oesophagus – patients may describe feeling of food sticking in the chest after swallowing and that food is moving slowly.⁹

Symptoms in adolescents and adults typically include:¹⁰

Food bolus obstruction

Retrosternal discomfort/ chest pain

Drinking lots of water with meals

Abnormal eating habits, such as eating small pieces of food and excessive chewing

Dysphagia to solids

How is EoE diagnosed?



Delays in the diagnosis of EoE and consequent delays in beginning treatment can impact significantly on patients.¹

EoE is diagnosed by an oesophago-gastro-duodenoscopy (OGD). A minimum of six biopsies should be taken from multiple sites (ideally three) to ensure the diagnosis of EoE.¹ Six biopsies are preferred, bringing the ability to diagnosis EoE correctly from 55% from a single biopsy to around 100%.¹¹ EoE is diagnosed when the oesophageal epithelium has >15 eosinophils in a surface area of 0.3 mm².⁷

*Formerly per high-power field.



“Six biopsies taken from multiple sites (ideally three) of the oesophagus”

Treatment



Budesonide orodispersible tablets (ODT) is the only treatment licensed for EoE in the UK.¹²

Budesonide ODT is highly effective at inducing and maintaining remission in EoE.^{13,14}



With budesonide ODT, symptoms are controlled in **80% of patients** for at least three years.^{14,15}

Other treatment options such as dietary exclusions should be under the supervision and guidance of a dietitian. Proton pump inhibitors (PPIs) may be considered depending on patient symptoms.¹

Call to action

- 1 Ensuring rapid access to testing and diagnosis for patients with suspected EoE is critical.
- 2 Initiating the right treatment promptly and ensuring continued access to this treatment is key.
- 3 Trusts and Integrated Care Systems should work together more smartly to ensure that patients have continued access to treatment for maintenance of this long-term condition in the community.



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Adverse events should be reported. In the UK visit www.mhra.gov.uk/yellowcard. In Ireland: 0044.001628.536600. Adverse events should also be reported to Dr Falk Pharma UK Ltd on dr.falk@drfalkpharma.com or 0044 (0)1628 536600.

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 oesophagitis (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 esophageal 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. 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 esophageal 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. Patient response 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 with ketoconazole or other 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 (withdrawing 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 - £323.05mg - pack of 60 - £214.80. Not currently available in Ireland. **Product licence holder:** Dr. Falk Pharma GmbH. **Product licence number:** IE/NL: EMU/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.

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