

Prescribing Information for Flixotide® (fluticasone propionate) Evohaler®, Accuhaler® – refer to the Summary of Product Characteristics (SPC) for further details and before prescribing

Indications: Evohaler and Accuhaler: Asthma prophylaxis. *Adults:*

Mild asthma - patients requiring intermittent symptomatic bronchodilator asthma medication on a regular daily basis.

Moderate asthma - patients with unstable or worsening asthma despite prophylactic therapy or bronchodilator alone.

Severe asthma - patients with severe chronic asthma and those who are dependent on systemic corticosteroids for adequate control of symptoms. On introduction of inhaled fluticasone propionate many of these patients may be able to reduce significantly, or to eliminate, their requirement for oral corticosteroids.

Children: any child who requires prophylactic medication, including patients not controlled on currently available prophylactic medication.

Dosage and Administration: For inhalation only. To be used regularly even when patient is asymptomatic. Start at a dose appropriate to disease severity. Titrate dose to the lowest dose at which effective control of asthma is maintained.

Adults and children over 16

Evohaler and Accuhaler: onset of therapeutic effect is within 4 to 7 days. Mild asthma: starting dose 100 micrograms twice daily. Moderate and more severe asthma: starting dose 250 to 500 micrograms twice daily. Severe asthma: up to 1000 micrograms twice daily only to be used in patients with severe asthma under specialist management, where additional clinical benefit is expected. If 50 microgram Flixotide Evohaler presentation does not offer the exact paediatric dose prescribed then refer to alternative presentations (Accuhaler, Nebules). Flixotide Evohaler may be used with a Volumatic® spacer device. Administration of high doses should be via a spacer device to reduce side effects in the mouth and throat. Initiation of high doses should be prescribed by a specialist in asthma management. Flixotide is as effective as other inhaled steroids at approximately half the microgram daily dose.

Children aged 4 and over

Evohaler and Accuhaler: 50 to 100 micrograms twice daily. For uncontrolled asthma: additional benefit may be obtained by increasing to a maximum dose of 200 micrograms twice daily.

Contraindications: Hypersensitivity to any ingredient of the preparation.

Precautions: Pulmonary tuberculosis, including quiescent. Increased blood glucose levels in patients with history of diabetes mellitus and non-diabetics. Sudden and progressive deterioration in asthma control is potentially life-threatening and consideration should be given to increasing corticosteroid dosage. In patients considered at risk, daily peak flow monitoring may be instituted. Treatment with Flixotide should not be stopped abruptly. *Severe or unstable asthma:* Warn patients to seek medical advice if short-acting inhaled bronchodilator use increases or becomes less effective. Consider increased doses of inhaled corticosteroids or a course of oral corticosteroids. The transfer of oral steroid-dependent patients to Flixotide Evohaler and their subsequent management needs special care as recovery from impaired adrenocortical function, caused by prolonged systemic steroid therapy, may take a considerable time. As with other inhalation therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. Flixotide Evohaler should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary. *Acute symptoms:* Not for relief of

acute symptoms. Use a short-acting inhaled bronchodilator.

Systemic effects: Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods, but are much less likely to occur than with oral corticosteroids (see adverse events). Prolonged treatment with high doses, particularly higher than recommended doses, may result in clinically significant adrenal suppression and acute adrenal crisis. Regularly monitor the height of children receiving prolonged treatment with inhaled corticosteroids. Recommended use of a spacer for administration of high doses. *Transfer from oral steroids:* Special care is needed. Consider additional corticosteroid therapy in situations likely to produce stress. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Flixotide Accuhaler.

Interactions: Avoid highly potent inhibitors of the cytochrome P450 3A4 e.g. ritonavir and less potent CYP3A inhibitors e.g.

ketokonazole and itraconazole. **Pregnancy and lactation:**

Experience is limited. Balance risks against benefits and titrate to lowest effective dose.

Adverse effects: See SPC for full details. Very common ($\geq 1/10$): candidiasis of mouth and throat. Common ($\geq 1/100$ and $< 1/10$): contusions, hoarseness/dysphonia, pneumonia in COPD patients. Other serious: rare ($\geq 1/10,000$ and $< 1/1000$) - oesophageal candidiasis; very rare ($< 1/10,000$) - hypersensitivity reactions including angioedema, respiratory symptoms (dyspnoea and/or bronchospasm) and anaphylactic reactions, Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decreased bone mineral density, cataract, glaucoma, hyperglycaemia; anxiety, sleep disorders, behavioural changes, including hyperactivity and irritability (predominantly in children); paradoxical bronchospasm (alternative therapy instituted if necessary). Frequency not known: blurred vision, depression, aggression (predominantly in children), epistaxis
Legal category: POM.

Marketing authorisation (MA) number(s) & Basic NHS costs:

Flixotide Evohaler: 120 actuations, 50 mcg: £6.53 (PL 10949/0324); 125 mcg: £21.26 (PL 10949/0265); 250 mcg: £36.14 (PL 10949/0266).

Flixotide Accuhaler: 60 inhalations, 50 mcg: £4.00 (PL 10949/0226); 100 mcg: £8.00 (PL 10949/0227); 250 mcg: £25.51 (PL 10949/0228); 500 mcg: £43.37 (PL 10949/0229).

MA Holder: Glaxo Wellcome UK Ltd, trading as GlaxoSmithKline UK, 980 Great West Road, Brentford, Middlesex, TW8 9GS.

Date of preparation: September 2020 (PI-5582). Flixotide Evohaler, Accuhaler and Volumatic are trademarks of the GlaxoSmithKline group of companies.

Adverse events should be reported. Reporting forms and information can be found at

<https://yellowcard.mhra.gov.uk/> or search for MHRA

Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to

GlaxoSmithKline on 0800 221 441.