Flixotide (fluticasone propionate) Evohaler and Accuhaler Prescribing Information.

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Flixotide Evohaler: pressurised inhalation suspension delivering 50 micrograms (mcg), 125 mcg or 250 mcg of fluticasone propionate.
Flixotide Accuhaler: plastic device with blisters each containing microfine fluticasone propionate (50 mcg, 100 mcg, 250 mcg or 500 mcg) and larger particle size lactose.
Indication: Prophylactic treatment for asthma
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 Flixotide many of these patients may be able to reduce significantly, or to eliminate, their requirement for oral corticosteroids.
Children: Evohaler 50 mcg, Accuhaler 50 mcg and Accuhaler 100 mcg devices only. Any child who requires prophylactic medication, including patients not controlled on currently available prophylactic medication.
Dosage and Administration: For oral inhalation only. To be used regularly even when asymptomatic. Start at a dose appropriate to disease severity. Onset of therapeutic effect is within 4 to 7 days. Dose may be increased until control is achieved or reduced to the minimum effective dose. Flixotide Evohaler may be used with a Volumatic spacer device.
Adults and children over 16 years: 100 to 1000 mcg twice daily. Typical starting doses: Mild asthma – 100 mcg twice daily; moderate or severe asthma – 250 mcg to 500 mcg twice daily. Where additional clinical benefit is expected, doses of up to 1000 micrograms twice daily may be used. Initiation of such doses should be prescribed only by an asthma management specialist. Doses above 500 mcg twice daily should be prescribed only for adults with severe asthma where additional clinical benefit is expected, demonstrated by either an improvement in pulmonary function and/or symptom control, or by a reduction in oral corticosteroid therapy. Doses of Flixotide Evohaler above 500 mcg twice daily should be via a spacer device.
Children aged 4-16 years: Typical starting dose: 50 to 100 mcg twice daily. For children whose asthma is not sufficiently controlled, additional benefit may be obtained by increasing the dose up to the maximum licensed dose of 200 mcg twice daily.
Contraindications: Hypersensitivity to fluticasone propionate or any excipient (Evohaler: HFA 134a. Accuhaler: Lactose which contains milk protein).
Precautions: Monitor response clinically and by lung function tests.
Flixotide is not for relief of acute symptoms. Patients should have a fast- and short-acting inhaled bronchodilator.
Reports of increased blood glucose levels with or without diabetes mellitus.
Paradoxical bronchospasm may occur with immediate increased wheezing after dosing. Discontinue Flixotide immediately, and institute alternative therapy if necessary.
Systemic effects of corticosteroids may occur, particularly at high doses over prolonged periods.
Certain individuals can show greater susceptibility to the effects of Flixotide than most patients.
Due to possibility of impaired adrenal response, treat patients transferring from oral steroid therapy to Flixotide with special care, and regularly monitor adrenocortical function. See SmPC for further details regarding transfer from oral steroids.
Prolonged treatment with high doses of Flixotide may result in adrenal suppression and acute adrenal crisis. Consider additional systemic corticosteroid cover during stress or elective surgery.
Regularly monitor height of children receiving prolonged treatment with Flixotide. If growth is slowed, reduce the dose to the lowest dose at which maintains effective asthma control. Consider referral to paediatric respiratory specialist.Treat lack of response or severe asthma exacerbations by increasing dose of Flixotide and, if necessary, by giving systemic steroid and/or antibiotic if there is an infection.
Replacement of systemic steroids with Flixotide may unmask allergies such as allergic rhinitis or eczema.
Take special care in active or quiescent pulmonary tuberculosis.
Flixotide should not be stopped abruptly.
Ritonavir can greatly increase plasma fluticasone propionate concentration. Avoid concomitant use unless potential benefit outweighs risk. Concomitant use of other potent CYP3A inhibitors with Flixotide increases risk of systemic side effects.
Visual disturbance may be reported with Flixotide.
Flixotide Evohaler via a spacer may increase drug delivery to lungs, increasing risk of systemic adverse effects. A lower dose may be required.
Flixotide Evohaler technique should be checked regularly.
Flixotide Accuhaler should not be taken by patients with galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.
Common adverse events: Very common (≥1/10): candidiasis of mouth and throat. Common (≥1/100 and <1/10): contusions, hoarseness/dysphonia, pneumonia in COPD patients.
Other adverse events: Rare (≥1/10,000 and <1/1000): oesophageal candidiasis. Very rare (<1/10,000): Angioedema (mainly facial and oropharyngeal oedema), respiratory symptoms (dyspnoea and/or bronchospasm), 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, arthralgia, dyspepsia.
Uncommon (≥1/1000 and <1/100): Cutaneous hypersensitivity reactions.
Frequency not known: blurred vision, depression, aggression (predominantly in children), epistaxis.
Consult SmPC for other adverse reactions.
Legal classification: POM.
Marketing authorisation (MA) numbers and basic NHS cost:
Flixotide Evohaler: 120 actuations - 50 mcg: PL 10949/0324, £6.53; 125 mcg: PL 10949/0265, £21.26; 250 mcg: PL 10949/0266, £36.14.
Flixotide Accuhaler: 60 inhalations - 50 mcg: PL 10949/0226, £4.00; 100 mcg: PL 10949/0227, £8.00; 250 mcg: PL 10949/0228, £25.51; 500 mcg: PL 10949/0229, £43.37.

MA Holder: Glaxo Wellcome UK Ltd, trading as GlaxoSmithKline UK, GSK Medicines Research Centre, Gunnells Wood Road, Stevenage, Hertfordshire. SG1 2 NY. UK
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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.