

Prescribing Information: Fobumix Easyhaler

Fobumix Easyhaler 80 micrograms/4.5 micrograms, 160 micrograms/4.5 micrograms and 320 micrograms/9 micrograms, inhalation powder (budesonide and formoterol fumarate dihydrate)

Indication: Asthma: 80/4.5: indicated in adults, adolescents and children 6 years and older. 160/4.5 and 320/9: indicated in adults, adolescents 12 years and older. **All strengths:** Regular treatment of asthma where use of a combination (inhaled corticosteroid and long-acting β_2 adrenoceptor agonist) is appropriate: patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting β_2 agonist or patients already adequately controlled on both inhaled corticosteroid and long-acting β_2 agonist. 160/4.5 only: Indicated as reliever therapy for adults and adolescents 12 years and older with mild asthma. 80/4.5: not appropriate in patients with severe asthma. **COPD:** 160/4.5 and 320/9: Adults: Symptomatic treatment of patients with COPD with FEV1 < 70% predicted normal (post-bronchodilator) and an exacerbation history despite regular bronchodilator therapy. **Dosage and Administration:** Inhalation. **Asthma:** 80/4.5 and 320/9: Not intended for the initial management of asthma. **All strengths:** The dosage of the components is individual and should be adjusted to the severity of the disease. **Maintenance therapy:** Advise patients to have a separate rescue inhaler available at all times. 80/4.5 only: Children (6 years and older): 2 inhalations twice daily. 80/4.5 and 160/4.5: Adults: 1-2 inhalations twice daily, maximum 4 inhalations twice daily, Adolescents (12-17 years of age): 1-2 inhalations twice daily. 320/9: Adults: 1 inhalation twice daily, maximum 2 inhalations twice daily, Adolescents (12-17 years of age): 1 inhalation twice daily. **All strengths:** Titration to the lowest effective dose could include once daily use, when a long-acting bronchodilator and inhaled corticosteroid would be required to maintain control. Children under 6 years of age: not recommended. **Maintenance and reliever therapy:** 80/4.5 and 160/4.5 only: Advise patients to always have Fobumix Easyhaler available for rescue use at all times. Monitor closely for dose-related adverse effects in patients who frequently take high numbers of Fobumix Easyhaler as-needed inhalations. Adults and adolescents aged 12 and above: 2 inhalations daily taken as a single or divided dose; for 160/4.5 only, a maintenance dose of 2 inhalations twice daily may be appropriate. Rescue use: 1 additional inhalation as needed in response to symptoms; if symptoms persist after a few minutes, an additional inhalation should be taken, maximum 6 inhalations on any single occasion. A total daily dose of more than 8 inhalations is not normally needed; however, a total daily dose of up to 12 inhalations could be used for a limited period. Patients using more than 8 inhalations daily should be strongly recommended to seek medical advice. Children under 12 years: not recommended. **Reliever therapy:** 160/4.5 only: Patients should be advised to always have Fobumix Easyhaler available for rescue use. Preventative use of Fobumix Easyhaler for allergen- or exercise-induced bronchoconstriction should be discussed between physician and patient; the recommended use should take into consideration the frequency of need. In case of frequent need of bronchodilation

without corresponding need for an increased dose of inhaled corticosteroids, an alternative reliever should be used. **Dosing:** Adults and adolescents aged 12 and above: 1 inhalation as needed in response to symptoms; if symptoms persist after a few minutes, an additional inhalation should be taken, maximum 6 inhalations on any single occasion. If a patient finds the treatment less effective or experiences progressive deterioration of symptoms despite as needed therapy, the patient should seek medical attention as soon as possible. A total daily dose of more than 8 inhalations is not normally needed; however, a total daily dose of up to 12 inhalations could be used for a limited period. Patients using more than 8 inhalations daily should be reassessed for alternative explanations of persisting symptoms. Patients should be assessed at regular intervals according to local practice to determine whether their as needed treatment remains optimal or whether regular scheduled treatment with inhaled corticosteroid-containing maintenance medication should be initiated. Children under 12 years: not recommended. **COPD 160/4.5:** Adults: Two inhalations twice daily. 320/9: Adults: 1 inhalation twice daily. Children: not recommended. **Contraindications:** Hypersensitivity to budesonide, formoterol, lactose or milk proteins. **Warnings and Precautions:** Do not initiate during an exacerbation. Advise patients to seek medical advice if asthma symptoms remain uncontrolled or worsen. Do not stop abruptly. Sudden and progressive deterioration in control of asthma or COPD is potentially life-threatening, patient should undergo urgent medical assessment. Consider reducing the dose once asthma symptoms are controlled; the lowest effective dose should be used. Paradoxical bronchospasm may occur, treatment should be stopped immediately. Systemic effects may occur, particularly with high doses prescribed for long periods; consider potential effects on bone density. Re-evaluate treatment in patients with active or quiescent pulmonary tuberculosis, fungal and viral infections of airways. Monitor height of children receiving prolonged treatment. Refer patients with blurred vision or other visual disturbances to an ophthalmologist. Take care when transferring patients with impaired adrenal function from previous systemic steroid therapy. Prolonged treatment with high doses of inhaled steroids may be at risk of impaired adrenocortical function, consider additional systemic corticosteroid during periods of stress. Transfer of patients treated with oral corticosteroids to inhaled corticosteroid and their subsequent management requires special care. Rinse mouth with water after inhaling the maintenance dose to minimise risk of oral symptoms. **If thrush occurs, rinse mouth after as-needed inhalations as well.** Avoid concomitant treatment with itraconazole, ritonavir or other potent CYP3A4 inhibitors. Caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, active or quiescent tuberculosis, airways infections,

hypertrophic obstructive cardiomyopathy, idiopathic subvalvular aortic stenosis, severe hypertension, aneurysm, prolongation of the QTc interval or other severe cardiovascular disorders. Potentially serious hypokalaemia may result from high doses of β_2 -adrenoceptor agonists; particular caution in unstable and acute severe asthma, as this effect may be potentiated by hypoxia, and concomitant treatment with xanthine-derivatives, steroids and diuretics; monitor serum potassium levels. In COPD, be vigilant for the possible development of pneumonia. Contains lactose; the amount does not normally cause problems in lactose intolerant people. The excipient lactose contains small amounts of milk proteins, which may cause allergic reactions. **Fertility, pregnancy and lactation:** Balance benefits against risks. **Undesirable Effects:** The most common adverse reactions, such as tremor and palpitations, tend to be mild and usually disappear within a few days of treatment. **Common:** candida infections in the oropharynx, headache, tremor, palpitations, mild irritation in throat, coughing, dysphonia including hoarseness, pneumonia in COPD patients. **Uncommon:** aggression, psychomotor hyperactivity, anxiety, sleep disorders, dizziness, blurred vision, tachycardia, nausea, bruises, muscle cramps. **Other undesirable effects:** Immediate and delayed hypersensitivity reactions (e.g. exanthema, urticaria, pruritus, dermatitis, angioedema and anaphylactic reaction), hypokalaemia, cardiac arrhythmias (e.g. atrial fibrillation, supraventricular tachycardia, extrasystoles), bronchospasm, Cushing's syndrome, adrenal suppression, growth retardation, decrease in bone mineral density, hyperglycaemia, depression, behavioural changes (predominantly in children), taste disturbance, cataract and glaucoma, angina pectoris, prolongation of QTc interval, variations in blood pressure. Prescribers should consult the SmPC in relation to other side effects. **Legal Category:** POM. **Product Authorisation Numbers:** Fobumix Easyhaler 80/4.5, inhalation powder: 120 actuations, £21.50 PL 27925/0090. Fobumix Easyhaler 160/4.5, inhalation powder: 60 actuations, £10.75, 120 actuations £21.50 PL 27925/0091. Fobumix Easyhaler 320/9, inhalation powder: 60 actuations, £21.50 PL 27925/0092. **Marketing Authorisation Holder:** Orion Corporation, Orionintie 1, FI-02200 Espoo, Finland. Distributed by Orion Pharma (UK) Ltd, 9th Floor, The Blade, Abbey Square, Reading, RG1 3BE, UK. Full prescribing information is available on request. Easyhaler is a registered trademark.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to Orion Pharma (UK) Ltd on 01635 520300.