

## Prescribing Information

### 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:** Fobumix Easyhaler is indicated in adults 18 years and older. **Asthma All strengths:** Regular treatment of asthma where use of a combination (inhaled corticosteroid and long-acting  $\beta_2$  adrenoceptor agonist) is appropriate. **80/4.5:** not appropriate in patients with severe asthma. **COPD 160/4.5 and 320/9:** Symptomatic treatment of patients with COPD with FEV<sub>1</sub> < 70% predicted normal (post-bronchodilator) and an exacerbation history despite regular bronchodilator therapy. **Dosage and Administration: Asthma:** Not intended for the initial management of asthma. The dosage of the components is individual and should be adjusted to the severity of the disease. **Maintenance therapy: 80/4.5 and 160/4.5:** Adults: 1-2 inhalations twice daily, maximum 4 inhalations twice daily. **320/9:** Adults: 1 inhalation twice daily, maximum 2 inhalations 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: 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: 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: 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. Not intended for regular prophylactic use, e.g. before exercise. Systemic effects may occur, particularly with high doses prescribed for long periods; consider potential effects on bone density. 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. 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  $\beta_2$ -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. **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, Abbey Gardens, 4 Abbey Street, Reading, RG1 3BA, 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](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Orion Pharma (UK) Ltd on 01635 520300