

Prescribing Information: Formoterol Easyhaler

Formoterol Easyhaler® 12 micrograms/dose inhalation powder (formoterol fumarate dihydrate)

Indication: Treatment of asthma in patients treated with inhaled corticosteroids and who also require a long-acting beta₂ - agonist; relief of reversible airways obstruction in patients with COPD needing long-term bronchodilators.

Dosage and administration:

Inhalation. *Adults (including elderly), and adolescents over 12 years: Asthma* - One inhalation twice daily, increasing to a maximum of two inhalations twice daily if necessary. *COPD* - One inhalation twice daily. *Children 6-12 years: Asthma* - One inhalation twice daily. Maximum 24mcg daily. *COPD* - Not appropriate. Not recommended in children under the age of 6. Treatment should aim for the lowest effective dose. *Renal and hepatic impairment:* No data. Increased exposure expected in severe liver cirrhosis.

Contraindications:

Hypersensitivity to the active substance, lactose or milk proteins.

Warnings and Precautions:

Should not be used as first treatment for asthma. Patients with asthma should receive optimal maintenance therapy with corticosteroids and must be advised to continue this even if symptoms decrease. Reassess if symptoms persist. Do not initiate during an acute exacerbation. Consider reducing the dose once symptoms are controlled; the lowest effective dose should be used. Frequent need of medication for prevention

of exercise-induced bronchoconstriction despite adequate maintenance treatment warrants reassessment. Caution in patients with severe hypertension, severe heart failure, ischaemic heart disease, cardiac arrhythmias, idiopathic subvalvular aortic stenosis, hypertrophic obstructive cardiomyopathy, thyrotoxicosis, phaeochromocytoma, aneurysm, known or suspected prolongation of the QTc interval and in patients treated with drugs affecting the QTc interval. Formoterol may cause QTc prolongation. Caution with concomitant use of theophylline in patients with cardiac conditions. Additional blood glucose controls are recommended for diabetic patients. Potentially serious hypokalaemia may result from beta₂-agonist therapy; particular caution in acute severe asthma, as this effect may be potentiated by hypoxia and concomitant treatment with xanthine derivatives, steroids, diuretics. Monitor serum potassium levels. Paradoxical bronchospasm may occur, treatment should be discontinued immediately. Not suitable for patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.

Fertility, pregnancy and lactation:

Balance benefits against risks.

Undesirable effects: Most commonly reported adverse events, such as tremor, palpitations and headache, tend to be mild and disappear within a few days of treatment. *Uncommon:* Agitation, restlessness, anxiety,

sleep disturbances, muscle cramps, myalgia, tachycardia. *Serious undesirable effects:* Hypersensitivity reactions such as bronchospasm, severe hypotension, urticaria, angioedema, pruritus, exanthema, peripheral oedema, hypokalaemia, cardiac arrhythmias e.g. atrial fibrillation supraventricular tachycardia, extrasystoles, aggravated bronchospasm, paradoxical bronchospasm, oropharyngeal irritation, nausea, dizziness, hyperglycaemia, angina pectoris, prolongation of QTc interval, variation in blood pressure. Prescribers should consult the SmPC in relation to other side effects. **Legal Category:** POM. **Product Authorisation Numbers:** Formoterol Easyhaler 12 micrograms per actuation inhalation powder: 120 actuations, £23.75 PL 27925/0050. **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