

## Prescribing Information: Beclometasone Easyhaler

### Easyhaler® Beclometasone 200 micrograms/dose inhalation powder (beclometasone dipropionate)

**Indication:** Prophylactic management of mild, moderate, or severe asthma in adults.

**Dosage and administration:** Oral inhalation. Starting dose should be appropriate to the severity of disease. Dose may be adjusted until control is achieved, or reduced to minimum effective dose according to individual response. Adults (including older people): Usual starting dose 200 micrograms twice a day, up to 600 to 800 micrograms per day in more severe cases. Total daily dose may be administered as two, three, or four divided doses. Children: Not recommended.

**Contraindications:** Hypersensitivity to beclometasone, lactose or milk proteins. Special care in patients with active or quiescent pulmonary tuberculosis.

**Warnings and precautions:** Ensure patient has correct inhaler technique and understands prophylactic nature of therapy. Not for relief of acute asthma symptoms; advise patients to have rescue medication available. Regularly assess patients with severe asthma. Increasing use of bronchodilators indicates deterioration of asthma control; consider increasing anti-inflammatory therapy. Systemic effects may occur; titrate dose to lowest effective level. Monitor

height of children receiving prolonged treatment. Refer patients with blurred vision or other visual disturbances to an ophthalmologist. Prolonged treatment with high doses may cause adrenal suppression. Patients transferred from oral steroids should be monitored regularly and their dose of systemic steroid reduced cautiously. Treatment should not be stopped abruptly. Care is needed in pulmonary tuberculosis. Caution and monitoring with concomitant strong CYP3A inhibitors. Not suitable for patients with galactose intolerance, the Lapp lactase deficiency or glucose galactose malabsorption.

**Fertility, pregnancy and lactation:**

Balance benefits against risks.

**Undesirable effects:**

Very common: oropharyngeal candidiasis. Common: hoarseness, throat irritation, cough. Uncommon: Hypersensitivity reactions with rash, urticaria, pruritus, erythema. Serious undesirable effects: Hypersensitivity reactions with oedema of the eyes, face, lips and throat, respiratory symptoms and anaphylactoid/ anaphylactic reactions. Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral

density, cataract, glaucoma, paradoxical bronchospasm, psychomotor hyperactivity, sleep disorders, anxiety, depression, aggression, behavioural changes (predominantly in children), eosinophilic pneumonia, easy bruising, skin thinning, vision blurred. Prescribers should consult the SmPC in relation to other side effects. **Legal Category:** POM. **Product Authorisation Numbers:** Easyhaler Beclometasone 200 micrograms/dose inhalation powder: 200 actuations, £14.93 PL 27925/0001. **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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**Job Code:** REF-00864

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