Prescribing Information: Budesonide Easyhaler

Easyhaler® Budesonide 100 micrograms, 200 micrograms and 400 micrograms/dose inhalation powder (budesonide)

Indication: Treatment of mild, moderate or severe persistent asthma for patients aged 6 years and above. **Dosage and administration:** Inhalation Adjust according to individual patient need including transfer from other inhaler devices. *Mild asthma:* Adults (including the elderly and adolescents 12-17 years) and for children 6-11 years: 200-400 mcg/day, up to 800 mcg/day. *Moderate and severe asthma:* Adults and adolescents 12-17 years: up to 1600 mcg/day. *Maintenance dose:* Twice daily dosing adults and adolescents 12-17 years: 100-400 mcg twice daily. During periods of severe asthma, daily dose may be increased up to 1600 mcg in two divided doses and reduced when asthma has stabilised. Children aged 6-11 years: 100-200 mcg twice daily up to 800 mcg in two doses. Reduce dose when asthma has stabilised. *Once daily dosing in mild to moderate asthma:* In inhaled corticosteroid (ICS)- naïve adult and adolescents patients aged 12-17 years: 200-400 mcg and in patients already controlled on ICS: up to 800 mcg; children aged 6-11 years: 200-400 mcg. Take once daily dose in the evening. Advise patients to have rescue medication available at all times. **Contraindications:** Hypersensi-tivity to budesonide, lactose or milk proteins. **Warnings and precautions:** Not for treatment of acute dyspnoea or status asthmaticus. Must be used regularly and should not be stopped abruptly. Patients who have used high dose emergency steroid therapy or prolonged treatment with high doses of inhaled steroids may be at risk of impaired adrenocortical function and may need supplementary systemic corticosteroid during periods of stress. Transfer of patients treated with oral corticosteroids to the inhaled corticosteroid and their subsequent management requires special care. Paradoxical bronchospasm may occur, budesonide should be discontinued immediately. Systemic effects may occur with high doses; titrate dose to lowest effective level. For patients with infections of the airways, including pulmonary tuberculosis, special care and adequate control of infection is required before commencing treatment. Monitor height of children receiving prolonged treatment. Reduced liver function affects the elimination of corticosteroids. Avoid concomitant cobicistat, HIV protease inhibitors or other potent CYP3A4 inhibitors, if benefit outweighs risk, monitor for systemic corticosteroid side effects. Refer patients with blurred vision or other visual disturbances to an ophthalmologist. Rinse mouth with water after inhaling to minimise risk of oral symptoms. Not suitable for patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose galactose malabsorption. **Fertility, pregnancy and lactation**: Balance benefits against risks. **Undesirable effects:** *Common:* cough and throat irritation, oropharyngeal candidiasis, difficulty in swallowing. *Uncommon:* anxiety, depression, cataract, blurred vision, muscle spasm, tremor. *Serious undesirable effects include:* Hypersensitivity reactions (including angioedema and anaphylactic reaction), hypocorticism, hypercorticism, adrenal suppression, growth retardation, behavioural changes (mainly in children), bronchospasm, pruritus, erythema, bruising, glaucoma, decreased bone density, psychomotor hyperactivity, sleep disorders, aggression, psychosis. Prescribers should consult the SmPC in relation to other side effects. **Legal Category:** POM. **Product Authorisation Numbers:** Easyhaler Budesonide 100 micrograms per actuation inhalation powder: 200 actuations, £8.86 PL 27925/0008. Easyhaler Budesonide 200 micrograms per actuation inhalation powder: 200 actuations, £17.71 PL 27925/0009. Easyhaler Budesonide 400 micrograms per actuation inhalation powder: 100 actuations, £17.71 PL 27925/0010. **Marketing Authorisation Holder:** Orion Coporation, 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