Prescribing Information: Salbutamol Easyhaler

Easyhaler® Salbutamol Sulfate 100 micrograms and 200 micrograms per actuation inhalation powder (salbutamol sulfate)

Indication: Symptomatic treatment of asthma attacks and exacerbations of asthma in adults and children aged 4 years and over; prevention of exercise- induced bronchospasm or before unavoidable allergen exposure; symptomatic treatment of bron- choasthma and other conditions associated with reversible airways obstruction. **Dosage and administration: Oral inhalation**. Adults, older people and children aged 12 years and over: 100 and 200 mcg – Bronchospasm and intermittent episodes of asthma, 100-200mcg as a single dose, increasing to 200-400mcg if necessary. To prevent exercise or allergen induced bronchospasm, 200mcg before challenge, repeated if necessary. Children aged 4-11 years: 100-200 mcg for relief of acute bronchospasm, or before exercise or allergen exposure. Chronic therapy, 200mcg four times a day. On demand use should not exceed 800 mcg in 24 hour **Contraindications**: Hypersensitivity to salbutamol, lactose or milk proteins. Not for management of premature labour or threatened abortion. **Warnings and Precautions:** Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma; consider using oral corticosteroid or the maximum use of inhaled corticosteroids. If treatment fails to give relief for at least three hours or more inhalations are needed than usual medical attention should be sought. Regular anti-inflammatory thera-py is required if inhaled beta-agonists are needed more than twice a week. Overuse of short acting beta-agonists may lead to an increased risk of severe asthma exacerbations and mortality. Dosage and frequency of administration should only be increased on medical advice. Caution in patients with thyrotoxicosis, cardiac insufficiency, hypokalaemia, myocardial ischaemia, tachyarrhythmia and hypertrophic obstructive cardio-myopathy or using additional adrenergic drugs. Bronchospam may be caused after dosing in which case treatment should be discontinued immediately. Particular caution in acute severe asthma, as hypoka- laemia may be potentiated by concomitant treatment with xanthine derivatives, steroids, diuretics and hypoxia. Cardiovascular effects may be seen. Concomitant use with non-selective beta-blocking drugs are not recommended. Patients with underlying severe heart disease should seek medical advice if they experience chest pain or other cardiac symptoms. Assess symptoms such as dyspnoea and chest pain as they may be of respiratory or cardiac origin. Salbutamol can induce reversible metabolic changes such as increased blood glucose. Diabetic patients should be monitored, including for DKA. Monitor initial concomitant use with mono- amine oxidase inhibitors or tricyclic anti-depressants. 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:** Common: Palpitations, peripheral vasodilatation, and as a result small increase in heart rate, tremor. Uncommon: headache, hypersensitivity reactions (angioedema, urticaria, hypotension and collapse). Serious undesirable effects include: hypokalaemia, bronchospasm, myocardial ischaemia, cardiac arrhythmias. Prescribers should consult the SmPC in relation to other side effects. **Legal Category:** POM. **Product Authorisation Numbers:** Easyhaler Salbutamol Sulfate 100 micrograms per actuation inhalation powder: 200 actua- tions, £4.05 PL 27925/0002. Easyhaler Salbutamol Sulfate 200 micrograms per actuation inhalation powder: 200 actuations, £8.12 PL 27925/0003 **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