

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 bronchoasthma and other conditions associated with reversible airways obstruction.

Dosage and administration: *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 hours

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 therapy 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 cardiomyopathy or using additional adrenergic drugs. Particular caution in acute severe asthma, as hypokalaemia 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. Salbutamol can induce reversible metabolic changes such as increased blood glucose. Diabetic patients should be monitored. Assess symptoms such as dyspnoea and chest pain as they may be of respiratory or cardiac origin. Monitor initial concomitant use with monoamine 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 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. **Presentation, cost and marketing authorisation number:** Easyhaler Salbutamol Sulfate 100 micrograms per actuation inhalation powder; 200 actuations £3.31 PL 27925/0002. Easyhaler Salbutamol Sulfate 200 micrograms per actuation inhalation powder 200 actuations, £6.63 PL 27925/0003 **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.

Date of prescribing information: February 2024

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