

Prescribing Information for Ventolin® (salbutamol) Evohaler® and Accuhaler®

(Please refer to the full Summary of Product Characteristics before prescribing)

Ventolin Evohaler® (salbutamol) is a pressurised metered-dose inhaler delivering 100 micrograms per actuation.

Ventolin Accuhaler® is a multi-dose dry powder inhalation device containing a foil strip with 60 regularly spaced blisters each containing a mixture of 200 micrograms of microfine salbutamol.

Indications: Short-acting bronchodilator used in the management of reversible airways obstruction e.g. asthma symptoms.

Dosage and administration:

Treatment should be under the supervision of specialists in respiratory medicine. Inhalation only.

Children (aged 4-11), adolescent, adults- Evohaler:

One inhalation (100 mcg) may be administered as a single minimum starting dose. May be increased to two inhalations if necessary. Maximum dose should not exceed 8 inhalations in any 24 hours.

Accuhaler: 200 micrograms as a single dose. The maximum daily dose is 200 micrograms four times a day.

Ventolin Evohaler may be used with a Volumatic™ spacer device. Babyhaler™ spacer device may be used to facilitate administration for children under 5 years of age.

Contraindications: Hypersensitivity to salbutamol or any of the excipients. Must not be used to arrest uncomplicated premature labour or threatened abortion.

Precautions: *Inhaler technique should be checked to make sure that aerosol actuation of Evohaler is synchronised with inspiration of breath for optimum delivery of drug to the lungs.*

The dosage or frequency of administration should only be increased on medical advice. Bronchodilators should not be the only or main treatment in severe or unstable asthma.

Physicians should consider using the maximum recommended dose of inhaled corticosteroid and/or oral corticosteroid therapy in these patients.

Patients should be instructed to seek medical advice if short-acting relief bronchodilator treatment becomes less effective e.g. previously effective dose fails to give relief lasting at least 3 hours, or more inhalations than usual are required.

Cardiovascular effects may be seen. There is some evidence of rare occurrences of myocardial ischaemia.

Patients with underlying severe heart disease (e.g. ischaemic heart disease, arrhythmia or severe heart failure) should be warned to seek medical advice if they experience chest pain or

other symptoms of worsening heart disease.

Administer cautiously in patients with thyrotoxicosis. Serious hypokalaemia may result from β 2-agonist therapy.

Particular caution is advised in acute severe asthma as this effect may be potentiated by hypoxia and by concomitant treatment with xanthine derivatives, steroids and diuretics.

Serum potassium levels should be monitored in such situations. As with other inhalation therapy, paradoxical bronchospasm may occur.

Ventolin Evohaler/Accuhaler should be discontinued immediately, the patient assessed, and if necessary, a different fast-acting bronchodilator instituted for on-going use.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not use Ventolin Accuhaler.

Interactions: Salbutamol and non-selective β -blocking drugs such as propranolol should not be prescribed together.

Fertility, pregnancy and lactation: Limited published evidence. Do not use in pregnancy unless clearly necessary. Use in breast-feeding mothers should be restricted to situations where expected benefit to the neonate, as salbutamol is probably secreted in breast milk.

Side effects: Common ($\geq 1/100$ to $< 1/10$): Tremor, Headache, Tachycardia. Rare ($\geq 1/10,000$ to $< 1/1000$): Hypokalaemia, Peripheral vasodilatation. Very rare ($< 1/10,000$) Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse, hyperactivity cardiac arrhythmias, paradoxical bronchospasm.

Unknown: Myocardial ischaemia

Legal category: POM. **Marketing authorisation (MA) number(s), Presentation and Basic NHS cost:**

Ventolin Evohaler: 100mcg per dose, 200 actuations: £1.50. (PL 10949/0274)

Ventolin Accuhaler: 60 inhalations, 200mcg: £3.60 (PL 10949/0252).

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Adverse events should be reported. Reporting forms and information can be found at yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.