

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

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

### Quantitative list of active ingredients:

**Ventolin Evohaler:** pressurised metered-dose inhaler delivering 100 micrograms (mcg) salbutamol (as salbutamol sulfate BP) per actuation.

**Ventolin Accuhaler:** plastic inhaler device with blisters each containing 200 mcg microfine salbutamol (as sulfate) and 12.5 milligrams (mg) larger particle lactose monohydrate.

### Indications:

**Ventolin Evohaler:** indicated in patients aged  $\geq 4$  years. Short-acting (4 to 6 hour) bronchodilation with fast onset (within 5 minutes) in reversible airways obstruction. For relief and prevention of asthma symptoms. Use to relieve symptoms when they occur, and prevent them in circumstances recognised to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure). Use as relief medication in mild, moderate, or severe asthma, provided that reliance on it does not delay use of regular inhaled corticosteroid.

**Ventolin Accuhaler:** indicated in patients aged  $\geq 4$  years for management of asthma, bronchospasm and/or reversible airways obstruction. For relief of asthma symptoms when they occur, and to prevent them in circumstances recognised to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure).

**Dosage and administration:** Oral inhalational use only. Maximum on-demand dose is 8 inhalations in 24 hours.

**Ventolin Evohaler:** May be used with Volumatic spacer device.

**Patients aged  $\geq 12$  years:** For relief of acute asthma including bronchospasm, one inhalation (100 mcg) as a single minimum starting dose, increased to two inhalations if necessary. To prevent allergen- or exercise-induced symptoms, two inhalations 10-15 minutes before challenge. For chronic therapy, two inhalations up to four times a day. **Children  $< 12$  years:** Usual dose for relief of acute bronchospasm is one inhalation (100 mcg), increased to two inhalations if required. Usual dose for prevention of allergen- or exercise-induced bronchospasm is one inhalation (100mcg) before challenge or exertion, increased to two inhalations if required. Usual dose for chronic therapy is up to two inhalations 4 times daily. Babyhaler spacer device may be used to facilitate administration in children  $< 5$  years.

**Ventolin Accuhaler: Patients aged  $\geq 12$  years:** For relief of acute bronchospasm, 200 mcg as a single dose. Maximum daily dose is 200 mcg four times a day. To prevent allergen- or exercise-induced symptoms, 200 mcg should be taken 10-15 minutes before challenge. **Children aged 4-11 years:** For relief of acute bronchospasm, 200 mcg as required. For prevention of allergen- or exercise-induced bronchospasm, 200 mcg before challenge or exertion. For chronic therapy, 200 mcg four times a day.

**Contraindications:** Hypersensitivity to salbutamol or any of the excipients (HFA 134a for Evohaler; lactose for Accuhaler). Not to be used to arrest uncomplicated premature labour or threatened abortion. Ventolin Accuhaler contraindicated in severe milk-protein allergy.

**Precautions:** Bronchodilators should not be the only or main treatment in severe or unstable asthma.

Increase dosage or frequency only on medical advice.

Increasing use of bronchodilators to relieve symptoms (in particular short-acting inhaled  $\beta_2$ -agonists) to relieve symptoms indicates deterioration of asthma control. Overuse of short-acting  $\beta_2$ -agonists may mask the progression of the underlying disease and contribute to deteriorating asthma control, leading to an increased risk of severe asthma exacerbations and mortality. Patients who take more than twice a week "as needed" salbutamol, not counting prophylactic use prior to exercise, should be re-evaluated as these patients are at risk for overuse of salbutamol.

Cardiovascular effects may be seen, including rare occurrences of myocardial ischaemia. Patients with underlying severe heart disease should seek medical advice if experiencing symptoms of worsening heart disease. Dyspnoea and chest pain may be of either respiratory or cardiac origin.

Administer salbutamol cautiously in thyrotoxicosis.

Potentially serious hypokalaemia may result from Ventolin therapy. Particular caution advised in acute severe asthma as this effect may be potentiated by hypoxia and concomitant treatment with xanthine derivatives, steroids and diuretics. Monitor serum potassium levels in such situations.

Paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. Discontinue inhaled Ventolin and treat immediately with alternative presentation or different fast-acting inhaled bronchodilator.

Ventolin Accuhaler not to be taken in galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

Check Ventolin Evohaler inhaler technique to ensure aerosol actuation is synchronised with inspiration.

**Interactions:** Ventolin and non-selective  $\beta$ -blocking drugs such as propranolol should not be prescribed together. **Pregnancy and lactation:** Do not use in pregnancy unless clearly necessary. Use in nursing mothers should be restricted to situations where expected benefit to mother likely to outweigh potential risk to neonate.

**Common side effects:**  $\geq 1/100$  to  $< 1/10$ : Tremor, headache, tachycardia.

**Other side effects:** *Uncommon* ( $\geq 1/1000$  to  $< 1/100$ ): Palpitations, muscle cramps, mouth and throat irritation. *Rare* ( $\geq 1/10,000$  to  $< 1/1000$ ): Hypokalaemia (potentially serious), peripheral vasodilatation. *Very rare* ( $< 1/10,000$ ): Hypersensitivity reactions (including angioedema, urticaria, bronchospasm, hypotension, collapse), hyperactivity, cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia, extrasystoles), paradoxical bronchospasm. *Unknown frequency:* Myocardial ischaemia.

See SmPC in relation to other adverse reactions.

**Legal category:** POM.

**Marketing Authorisation (MA) number(s), Presentation and Basic NHS cost:** *Ventolin Evohaler:* 100mcg, 200 actuations: £1.50 (PL 10949/0274). *Ventolin Accuhaler:* 200mcg, 60 inhalations: £1.99 (PL 10949/0252).

**MA Holder:** Glaxo Wellcome UK Ltd, trading as GlaxoSmithKline UK, GSK Medicines Research Centre, Gunnels Wood Road, Stevenage, Hertfordshire. SG12NY.UK

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Adverse events should be reported. Reporting forms and information can be found at <https://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.