

# Ventolin

100mcg/ actuation Inhaler  
Bronchodilator

## PRODUCT DESCRIPTION

Each Salbutamol (*Ventolin*) Inhaler is a pressurised metered-dose inhaler which delivers salbutamol sulfate equivalent to 100mcg Salbutamol per actuation, into the mouthpiece of a specially designed actuator. The inhaler also contains the CFC-free propellant HFA 134a. Each canister contains at least 200 actuations.

## PHARMACOLOGIC PROPERTIES

### Pharmacodynamics

Salbutamol is a selective beta<sub>2</sub>-adrenoreceptor agonist. At therapeutic doses it acts on the beta<sub>2</sub>-adrenoreceptors of bronchial muscle providing short acting (4 to 6 hour) bronchodilation with a fast onset (within 5 minutes) in reversible airway obstruction.

### Pharmacokinetics

#### **Absorption**

After administration by the inhaled route, between 10 and 20% of the dose reaches the lower airways. The remainder is retained in the delivery system or is deposited in the oropharynx from where it is swallowed. The fraction deposited in the airways is absorbed into the pulmonary tissues and circulation but is not metabolised by the lung.

#### **Distribution**

Salbutamol is bound to plasma proteins to the extent of 10%.

#### **Metabolism**

On reaching the systemic circulation, salbutamol becomes accessible to hepatic metabolism and is excreted, primarily in the urine, as unchanged drug and as the phenolic sulphate.

The swallowed portion of an inhaled dose is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulphate. Both unchanged drug and conjugate are excreted primarily in the urine.

#### **Elimination**

Salbutamol administered intravenously has a half-life of four to six hours and is cleared partly renally and partly by metabolism to the inactive 4'-O-sulphate (phenolic sulphate) which is also excreted primarily in the urine. The faeces are a minor route of excretion. The majority of a dose of salbutamol given intravenously, orally or by inhalation is excreted within 72 hours.

## Clinical Studies

### Special Patient Populations

Children < 4 years of age

Paediatric clinical studies conducted at the recommended dose (SB020001, SB030001, SB030002), in patients < 4 years with bronchospasm associated with reversible obstructive airways disease, show that the Inhaler has a safety profile comparable to that in children ≥ 4 years, adolescents and adults.

### Non-Clinical Information

In common with other potent selective beta-<sub>2</sub> receptor agonists, salbutamol has been shown to be teratogenic in mice when given subcutaneously. In a reproductive study, 9.3% of foetuses were found to have cleft palate, at 2.5 mg/kg, four times the maximum human oral dose. In rats,

treatment at the levels of 0.5, 2.32, 10.75 and 50mg/kg/day orally throughout pregnancy resulted in no significant foetal abnormalities. The only toxic effect was an increase in neonatal mortality at the highest dose level as the result of lack of maternal care. A reproductive study in rabbits revealed cranial malformations in 37% of foetuses at 50mg/kg/day, 78 times the maximum human oral dose.

In an oral fertility and general reproductive performance study in rats at doses of 2 and 50 mg/kg/day, with the exception of a reduction in number of weanlings surviving to day 21 postpartum at 50 mg/kg/day, there were no adverse effects on fertility, embryofetal development, litter size, birth weight or growth rate.

HFA 134a has been shown to be non-toxic at very high vapour concentrations, far in excess of those likely to be experienced by patients, in a wide range of animal species exposed daily for periods of two years.

## INDICATIONS

Salbutamol is a selective beta<sub>2</sub> adrenoreceptor agonist indicated for the treatment or prevention of bronchospasm. It provides short acting (four hours) bronchodilation in reversible airways obstruction due to asthma, chronic bronchitis and emphysema. For patients with asthma salbutamol may be used to relieve symptoms when they occur and to prevent them prior to a known trigger.

Bronchodilators should not be the only or main treatment in patients with persistent asthma. In patients with persistent asthma unresponsive to Salbutamol (*Ventolin*), treatment with inhaled corticosteroids is recommended to achieve and maintain control. Failing to respond to treatment with Salbutamol (*Ventolin*) may signal a need for urgent medical advice or treatment.

## DOSAGE AND ADMINISTRATION

Salbutamol (*Ventolin*) has a duration of action of 4 to 6 hours in most patients. Increasing use of beta<sub>2</sub> agonists may be a sign of worsening asthma. Under these conditions a reassessment of the patient's therapy plan may be required and concomitant corticosteroid therapy should be considered. As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice.

Salbutamol (*Ventolin*) Inhaler is administered by the inhaled route only. In patients who find co-ordination of a pressurised metered-dose inhaler difficult a spacer may be used with Salbutamol (*Ventolin*) Inhaler.

Babies and young children using the Salbutamol (*Ventolin*) Inhaler may benefit from the use of a paediatric spacer device with a face mask (for example the BABYHALER). (*See Clinical Studies*).

## RELIEF OF ACUTE BRONCHOSPASM

- **Adults**

100 or 200 micrograms.

- **Children**

100 micrograms. The dose may be increased to 200 micrograms if required.

## PREVENTION OF ALLERGEN OR EXERCISE-INDUCED BRONCHOSPASM

- **Adults**

200 micrograms before challenge or exertion.

- **Children**

100 micrograms before challenge or exertion. The dose may be increased to 200 micrograms if required.

## CHRONIC THERAPY

- **Adults**

Up to 200 micrograms 4 times daily.

- **Children**

Up to 200 micrograms 4 times daily.

On demand use of Salbutamol (*Ventolin*) should not exceed four times daily. Reliance on such supplementary use or a sudden increase in dose indicates deteriorating asthma (*see Warnings and Precautions*).

## **CONTRAINDICATIONS**

Salbutamol (*Ventolin*) is contraindicated in patients with a history of hypersensitivity to any of its components. Non-i.v. formulations of Salbutamol (*Ventolin*) must not be used to arrest uncomplicated premature labour or threatened abortion.

## **WARNINGS AND PRECAUTIONS**

The management of asthma should normally follow a stepwise programme, and patient response should be monitored clinically and by lung function tests.

Increasing use of short-acting bronchodilators, in particular beta-2 agonists to relieve symptoms indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed.

Sudden and progressive deterioration in asthma control is potentially life-threatening and consideration should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow monitoring may be instituted.

Salbutamol (*Ventolin*) should be administered cautiously to patients with thyrotoxicosis. Potentially serious hypokalaemia may result from beta-2 agonist therapy mainly from parenteral and nebulised administration.

Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids, diuretics and by hypoxia. It is recommended that serum potassium levels are monitored in such situations.

As with other inhalation therapy, paradoxical bronchospasm may occur, resulting in an immediate increase in wheezing after dosing. This should be treated immediately with an alternative presentation or a different fast-acting inhaled bronchodilator, if immediately available. Salbutamol (*Ventolin*) Inhaler should be discontinued, and if necessary a different fast-acting bronchodilator instituted for ongoing use.

In the event of a previously effective dose of inhaled Salbutamol (*Ventolin*) failing to give relief for at least three hours, the patient should be advised to seek medical advice in order that any necessary additional steps may be taken. Patients' inhaler technique should be checked to make sure that aerosol actuation is synchronised with inspiration of breath for optimum delivery of the drug to the lungs.

### **Effects on Ability to Drive and Use Machines**

None reported.

## **DRUG INTERACTIONS**

Salbutamol and non-selective beta-blocking drugs, such as propranolol, should not usually be prescribed together.

Salbutamol (*Ventolin*) is not contraindicated in patients under treatment with monoamine oxidase inhibitors (MAOIs).

## **PREGNANCY AND LACTATION**

### **Fertility**

There is no information on the effects of salbutamol on human fertility. There were no adverse effects on fertility in animals (*see Non-Clinical Information*).

## **Pregnancy**

Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus. During worldwide marketing experience, rare cases of various congenital anomalies, including cleft palate and limb defects have been reported in the offspring of patients being treated with Salbutamol (*Ventolin*). Some of the mothers were taking multiple medications during their pregnancies. As no consistent pattern of defects can be discerned, and baseline rate for congenital anomalies is 2 to 3%, a relationship with Salbutamol (*Ventolin*) use cannot be established.

## **Lactation**

As salbutamol is probably secreted in breast milk, its use in nursing mothers is not recommended unless the expected benefits outweigh any potential risk. It is not known whether salbutamol in breast milk has a harmful effect on the neonate.

## **ADVERSE EFFECTS**

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1000$  to  $< 1/100$ ), rare ( $\geq 1/10,000$  to  $< 1/1000$ ) and very rare ( $< 1/10,000$ ) including isolated reports. Very common and common events were generally determined from clinical trial data. Rare and very rare events were generally determined from spontaneous data.

### **Immune system disorders**

Very rare: Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse

### **Metabolism and nutrition disorders**

Rare: Hypokalaemia

Potentially serious hypokalaemia may result from beta<sub>2</sub> agonist therapy

### **Nervous system disorders**

Common: Tremor, headache

Very rare: Hyperactivity

### **Cardiac disorders**

Common: Tachycardia

Uncommon: Palpitations

Very rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles

### **Vascular disorders**

Rare: Peripheral vasodilatation

### **Respiratory, thoracic and mediastinal disorders**

Very rare: Paradoxical bronchospasm

### **Gastrointestinal disorders**

Uncommon: Mouth and throat irritation

### **Musculoskeletal and connective tissue disorders**

Uncommon: Muscle cramps

## **OVERDOSAGE AND TREATMENT**

The most common signs and symptoms of overdose with Salbutamol (*Ventolin*) are transient beta agonist pharmacologically mediated events (*see Warnings and Precautions and Adverse Reactions*).

Hypokalaemia may occur following overdose with Salbutamol (*Ventolin*). Serum potassium levels should be monitored.

Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting beta-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly if there is persistence or worsening of tachypnea despite resolution of other signs of bronchospasm such as wheezing) may be indicated in the

setting of overdose.

## **STORAGE**

Replace the mouthpiece cover firmly and snap it into position

Store at temperatures not exceeding 30°C. Protect from frost and direct sunlight.

As with most inhaled medications in aerosol canisters, the therapeutic effect of this medication may decrease when the canister is cold.

Pressurised container. Do not expose to temperatures higher than 50°C. The canister should not be broken, punctured or burnt, even when apparently empty.

## **USE AND HANDLING**

### **Testing your inhaler**

Before using for the first time, remove the mouthpiece cover by gently squeezing the sides of the cover, shake the inhaler well, and release two puffs into the air to make sure that it works. If it has not been used for

5 days or more, shake it well and release 2 puffs into the air to make sure that it works.

### **Using your inhaler**

1. Remove the mouthpiece cover by gently squeezing the sides of the cover.
2. Check inside and outside of the inhaler including the mouthpiece for the presence of loose objects.
3. Shake the inhaler well to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.
4. Hold the inhaler upright between fingers and thumb with your thumb on the base, below the mouthpiece.
5. Breathe out as far as is comfortable and then place the mouthpiece in your mouth between your teeth and close your lips around it but do not bite it.
6. Just after starting to breathe in through your mouth press down on the top of the inhaler to release Salbutamol (*Ventolin*) while still breathing in steadily and deeply.
7. While holding your breath, take the inhaler from your mouth and take your finger from the top of the inhaler. Continue holding your breath for as long as is comfortable.
8. If you are to take further puffs keep the inhaler upright and wait about half a minute before repeating steps three to seven.
9. Replace the mouthpiece cover by firmly pushing and snapping the cap into position.

### **IMPORTANT**

Do not rush Stages 5, 6 and 7. It is important that you start to breathe in as slowly as possible just before operating your Inhaler.

Practise in front of a mirror for the first few times. If you see 'mist' coming from the top of the inhaler or the sides of your mouth you should start again from stage two.

If your doctor has given you different instructions for using your inhaler, please follow them carefully. Tell your doctor if you have any difficulties. **CLEANING**

Your inhaler should be cleaned at least once a week.

1. Remove the metal canister from the plastic casing of the inhaler and remove the mouthpiece cover.
2. Rinse the actuator thoroughly under warm running water.
3. Dry the actuator THOROUGHLY inside and out.
4. Replace the metal canister and mouthpiece cover. **DO NOT PUT THE METAL CANISTER INTO WATER.**

## **AVAILABILITY**

Salbutamol (*Ventolin*) 100mcg/actuation Inhaler: 200 actuations per Metered Dose Inhaler

**CAUTION**

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.  
Keep all medicines out of reach of children.

For suspected adverse drug reaction, report to the FDA: [www.fda.gov.ph](http://www.fda.gov.ph) Seek medical attention immediately at the first sign of any adverse drug reaction.

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