

## VENTAMOL CFC-FREE METERED DOSE INHALER 100 mcg / ACTUATION

VIVENxx-02

### DESCRIPTION

10 ml white suspension aerosol dosed for 200 inhalations (MDI)

### COMPOSITION

Each inhalation contains 120 mcg of Salbutamol Sulphate (equivalent to Salbutamol 100 mcg).

### PHARMACODYNAMICS

Salbutamol is a selective  $\beta_2$ -adrenoceptor agonist. At therapeutic doses it acts on the  $\beta_2$ -adrenoceptors of bronchial muscle, with little or no action on the  $\beta_1$ -adrenoceptors of cardiac muscle.

Salbutamol provides short-acting (4-6 hour) bronchodilatation with a fast onset in reversible airways obstruction.

### PHARMACOKINETICS

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. On reaching the systemic circulation it 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. Almost all of a dose of salbutamol given intravenously, orally or by inhalation is excreted within 72 hours. Salbutamol is bound to plasma proteins to the extent of 10%.

### INDICATION

Relief and prevention of bronchospasm in bronchial asthma, chronic bronchitis, emphysema, acute dyspnoea.

### CONTRAINDICATIONS

Hypersensitivity to the active substance (Salbutamol) or to any of the excipients.

### WARNING AND PRECAUTIONS

Bronchodilators should not be the main treatment in patients with severe or unstable asthma. Severe asthma requires regular medical assessment, including lung-function testing, as patients are at risk of severe attacks and even death.

The dosage or frequency of administration should only be increased on medical advice.

Increasing use of bronchodilators, in particular short-acting inhaled  $\beta_2$ -agonists, to relieve symptoms, indicates deterioration of asthma control. The patient should be instructed to seek medical advice if short-acting relief bronchodilator treatment becomes less effective. Severe exacerbations of asthma must be treated in the normal way.

Cardiovascular effects may be seen with sympathomimetic drugs, including salbutamol. There is some evidence from post-marketing data and published literature of rare occurrences of myocardial ischaemia associated with salbutamol.

Salbutamol should be administered cautiously to patients with thyrotoxicosis.

Potentially serious hypokalaemia may result from  $\beta_2$ -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.

### INTERACTION

Use of salbutamol and other beta2 agonists with corticosteroids, diuretics or xanthines increases the risk of hypokalemia. Monitoring of potassium concentration is recommended in severe asthma.

### MAIN SIDE/ADVERSE EFFECTS

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

Unknown: Myocardial ischaemia

**VENTAMOL CFC-FREE METERED DOSE  
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Rare: Peripheral vasodilatation.  
Respiratory, thoracic and mediastinal disorders  
Very rare: Paradoxical bronchospasm.

As with other inhalation therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with an alternative presentation or a different fast-acting inhaled bronchodilator. Salbutamol should be discontinued immediately, the patient assessed, and, if necessary, alternative therapy instituted.

**Gastrointestinal disorders**

Uncommon: Mouth and throat irritation.  
Musculoskeletal and connective tissue disorders  
Uncommon: Muscle cramps.  
\* reported spontaneously in post-marketing data therefore frequency regarded as unknown

**PREGNANCY AND LACTATION**

The administration during pregnancy and lactation should only be considered if the expected benefit for the mother is greater than any potential risk for the foetus.

**OVERDOSE**

An overdose should be treated symptomatically.

The preferred antidote for overdosage with salbutamol is a cardioselective beta-blocking agent, but beta-blocking drugs should be used with caution in patients with a history of bronchospasm.

Hypokalaemia may occur following overdose with salbutamol. Serum potassium levels should be monitored.

**RECOMMENDED DOSE**

Inhalation use

Adults (including the elderly) and Children: For the relief of acute asthma symptoms and bronchospasm, one inhalation (100 micrograms) may be administered. This may be increased to two inhalations if necessary.

To prevent allergen- or exercise-induced symptoms, two inhalations should be taken 10-15 minutes before challenge.

For chronic therapy, two inhalations up to four times a day.

**INSTRUCTIONS OF USE / HANDLING:**

A. Remove the cap. Should it be a new inhaler or that hasn't been used for several days, shake the inhaler and actuate it to ensure its good performance. Should the inhaler be periodically used read the following instructions:

B. Shake the inhaler.

C. Exhale as much air as possible from your lungs.

D. Adapt the inhaler to your mouth according to the position indicated in the illustration.

E. Breathe in as deeply as possible. You should press the apparatus, while you are breathing in.

F. Remove the inhaler from your mouth and try to hold the air in your lungs for a few seconds.

G. The oral actuator-adapter should be regularly washed. In order to do it, remove the actuator from the inhaler and wash it with abundant water.

H. Store it with the cap on in order to protect it from dust and dirt.

The bronchodilator effect of each application of inhaled salbutamol lasts for at least four hours, except in patients whose asthma is worsening. These patients should be warned not to increase the use of the inhaler but to consult the doctor in case an increase in the dose of the treatment with inhaled or systematically administered glucocorticosteroids is needed.

The need for an additional use or a sudden increase in the dose shows a worsening of the asthmatic disease. As adverse effects related to extremely high doses may occur, the dose or the administration frequency should only be increased on the doctor's orders.

Note: The information given here is limited. For further information consult your doctor or pharmacist.

Storage : Store below 30°C. Protect from direct sunlight and do not freeze.  
Pressurized Inhaler : It should not be perforated, broken or burnt even when it is apparently empty.

Presentation/packing : Aluminium can with 200 actuations; Aluminium can with 300 actuations.  
Containing 100 mcg of salbutamol each, equipped with a metered dose valve, oral actuator-adapter and a cap.

Manufactured for: HOVID Bhd.  
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