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**PROFESSIONAL INFORMATION**

**SCHEDULING STATUS**

**S2**

## 1. NAME OF THE MEDICINE

**VENTSOL INHALER 100 µg** (Metered dose inhaler)

Contains Salbutamol sulfate 100 µg/actuation.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each actuation delivers 100 µg Salbutamol sulfate.

Sugar free

Excipients:

For a full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Aerosol

**VENTSOL INHALER 100 µg** Pressurised metered dose inhaler containing suspension aerosol filled in aluminum canister fitted with suitable metered valve. There should be no sign of physical damage or leakage.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

- **VENTSOL INHALER 100 µg** is indicated for relief of bronchospasm in:
- Bronchial asthma of all types
- Chronic bronchitis
- Emphysema

**4.2 Posology and method of administration**

***Posology:***

One or two inhalations, repeated four-hourly if required. The bronchodilator effect of each administration of **VENTSOL INHALER 100 µg** lasts for at least four hours and more frequent use should be unnecessary. The patient can readily recognise any reduction in the length of action and should be instructed to consult a medical practitioner *if* the effect of a previously adequate dose lasts for less than three hours.

**VENTSOL INHALER 100 µg** acts rapidly and may be used when necessary to relieve attacks of acute dyspnoea. Doses may be taken prophylactically before exertion to prevent exercise-induced asthma.

Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma. Severe asthma requires regular medical assessment as the condition is potentially life-threatening. Patients with severe asthma have constant symptoms and frequent exacerbations, with limited physical capacity, and PEF values below 60 % predicted at baseline with greater than

30 % variability, usually not returning entirely to normal after a bronchodilator. These patients will require inhaled corticosteroid therapy.

Failure to respond promptly or fully to such rescue medicine signals a need for urgent medical advice and treatment.

Do not exceed the recommended dose.

**Method of administration**

**VENTSOL INHALER 100 µg** is administered by the inhaled route only, to be breathed in through the mouth.

Patient’s inhaler technique should be checked to make sure that aerosol actuation is synchronised with inspiration of breath for optimum delivery of medicine to the lungs.

### 4.3 Contraindications

- **VENTSOL INHALER 100 µg** is contra-indicated in patients with hypersensitivity to salbutamol or any of its excipients listed in section 6.1.
- **VENTSOL INHALER 100 µg** is not appropriate for managing premature labour.
- **VENTSOL INHALER 100 µg** preparations should not be used for threatened abortion.

### 4.4 Special warnings and precautions for use

Patient's inhaler technique should be checked to make sure that aerosol actuation is synchronised with inspiration of breath for optimum delivery of medicine to the lungs. Patients should be warned that they may experience a different taste upon inhalation compared to their previous inhaler.

**VENTSOL INHALER 100 µg** should be administered cautiously to patients suffering from thyrotoxicosis.

**VENTSOL INHALER 100 µg** should be used with caution in patients with cardiovascular disorders especially ischaemic heart disease, angina, tachycardia, dysrhythmias and hypertension.

**VENTSOL INHALER 100 µg** should be used with caution in patients known to have received other sympathomimetic medicine.

**VENTSOL INHALER 100 µg** and beta-blocking medicines, such as propranolol should not be prescribed together.

Increasing use of **VENTSOL INHALER 100 µg** may be a sign of worsening asthma. Under these conditions, a reassessment of the patient's therapy plan may be required and concomitant glucocorticosteroid 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.

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

Increasing use **VENTSOL INHALER 100 µg** to control 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. In the event of a previously effective dose **VENTSOL INHALER 100 µg** 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.

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

High dosages may increase the risk of serious side effects, including cardiac dysrhythmias. The risk is further aggravated if administered concomitantly with other medicines that cause hypokalaemia and cardiac dysrhythmias or in the presence of hypoxia and acidosis. The maximum dose should not be exceeded.

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. **VENTSOL INHALER 100 µg** should be discontinued immediately, the patient assessed, and if necessary, a different fast-acting bronchodilator instituted for on-going use.

The amount of drug delivered to the lungs will depend on patient factors, such as inspiratory flow and peak inspiratory flow (PIF) through the delivery system, which may vary for asthma, COPD, and other patient populations.

**4.5 Interaction with other medicines and other forms of interaction**

Sympathomimetics should be used with caution in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics as ventricular fibrillation may be induced.

An increased risk of dysrhythmias may also occur if administered concomitantly with cardiac glycosides, quinidine or tricyclic antidepressants. Sympathomimetic amines should not be given to patients receiving mono-amine oxidase inhibitors or within 14 days of termination of mono-amine oxidase inhibitor therapy.

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

**4.6 Fertility, pregnancy and lactation**

*Pregnancy:*

Safety during pregnancy has not been established.

*Breast-feeding*

Safety during lactation has not been established.

*Fertility*

There is no information on the effects of salbutamol on human fertility. There were no adverse effects on fertility in animals.

**4.7 Effects on ability to drive and use machines**

None reported

**4.8 Undesirable effects**

The following adverse reactions have been reported in association with **VENTSOL INHALER 100 µg**

| System organ class | Frequency | Undesirable effect |
|---|---|---|
| **Immune system disorders** | Less frequent | Anaphylactoid reactions hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse |
| **Metabolism and nutrition disorders** | Less frequent | Potentially serious hypokalaemia |
| **Nervous system disorders** | Frequent | Tremor, headache |
| | Frequency not known* | Hyperactivity, agitation, nervousness, fatigue, fear, restlessness, dizziness, confusion, insomnia |

| | | |
|---|---|---|
| **Cardiac disorders** | Frequency not known* | cardiac dysrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles, myocardial ischaemia |
| | Frequent | Tachycardia |
| | Less frequent | Palpitations. |
| **Vascular disorders** | Frequency not known* | Peripheral vasodilatation |
| **Respiratory, thoracic and mediastinal disorders** | Frequency not known* | Paradoxical bronchospasm |
| **Gastrointestinal disorders** | Less frequent | loss of appetite, nausea, vomiting, mouth and throat irritation |
| **Musculoskeletal and connective tissue disorders** | Less frequent | Muscle cramps |

*reported spontaneously in post-marketing data therefore frequency regarded as unknown

*Reporting of suspected adverse reactions*

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

**4.9 Overdose**

Symptoms and Signs:

The most common signs and symptoms of overdose with **VENTSOL INHALER 100 µg** are beta agonist pharmacologically mediated events (see section 4.8).

Agitation, hallucinations and irritability have been reported.

Hypokalaemia may occur following overdose with **VENTSOL INHALER 100 µg**. Serum potassium levels should be monitored.

Treatment:

Consideration should be given to discontinuation of treatment and appropriate symptomatic therapy.

## 5. PHARMACOLOGICAL PROPERTIES

Category and Class: A 10.2.1 Medicines acting on respiratory system. Bronchodilators (Inhalants)

Pharmacotherapeutic group: Andrenergics, inhalants. Selective beta-2-andrenoreceptor agonists,

ATC code: R03AC02

### 5.1 Pharmacodynamic properties

Salbutamol is a beta-adrenergic stimulant which has a selective action on the receptors in bronchial muscle and, in therapeutic dosage, little or no action on the cardiac receptors. The action of **VENTSOL INHALER 100 µg** by inhalation is rapid; near maximal bronchodilatation occurring within five minutes.

### 5.2 Pharmacokinetic properties

**Absorption**

After administration by the inhaled route between 10 and 20 % of the dose is absorbed. 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**

Protein binding is negligible (10 %).

**Biotransformation**

Salbutamol is metabolised mainly by sulphation.

The swallowed portion of an inhaled dose is absorbed from the gastrointestinal tract and undergoes considerable first pass metabolism to the phenolic sulfate.

**Elimination**

Salbutamol is excreted in the urine, both as free drug and conjugated metabolite (phenolic sulphate).

The half-life ranges from 0,5 to 4 hours.

The majority of a dose of Salbutamol by inhalation is excreted within 72 hours.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

1,1,1,2 Tetrafluoroethane (Propellant HFA 134a)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

36 months from the date of manufacture.

### 6.4 Special precautions for storage

Store at or below 30 °C.

Replace the mouthpiece cover firmly and snap it into position.

Protect from frost and direct sunlight.

The canister should not be broken, punctured or burnt even when apparently empty.

KEEP OUT OF REACH OF CHILDREN.

### 6.5 Nature and contents of container

A 19 ml aluminium canister fitted with metered dispensing 50 µl nitrile valve crimped in place and a polypropylene actuator attached (dark blue coloured cap and light blue colour body), placed in a outer carton.

### 6.6 Special precautions for disposal and other handling

The aerosol spray is inhaled through the mouth into the lungs. After shaking the inhaler, the mouthpiece is placed in the mouth and the lips closed around it. The actuator is depressed to release a spray, which must coincide with inspiration of breath.

For detailed instructions for use refer to the Patient Information Leaflet in every pack.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

Macleods Pharmaceuticals SA (Pty) Ltd

Office Block 1, Bassonia Estate Office Park (East),

1 Cussonia Drive, Bassonia Rock, Ext. 12,

Alberton, South Africa.

## 8. REGISTRATION NUMBER(S)

54/10.2.1/0233

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/11/2022

## 10. DATE OF REVISION OF THE TEXT

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