

**PATIENT LEAFLET**  
**VENTOLIN INHALER CFC-FREE**  
**Salbutamol sulphate**

**Read all of this leaflet carefully before you start using this medicine.**

Keep this leaflet. You may need to read it again. If you have any questions, ask your doctor or pharmacist.

This medicine has been prescribed for you personally. Don't pass it on to other people - it may harm them even if their symptoms seem to be the same as yours.

**In this leaflet**

- 1. What VENTOLIN INHALER CFC-FREE is and what it is used for**
- 2. Before you use VENTOLIN INHALER CFC-FREE**
- 3. How to use VENTOLIN INHALER CFC-FREE**
- 4. Possible side effects**
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**1. What VENTOLIN INHALER CFC-FREE is and what it is used for**

VENTOLIN INHALER CFC-FREE contains a medicine called salbutamol. This belongs to a group of medicines called fast-acting bronchodilators. Fast-acting bronchodilators relax the muscles in the walls of the small airway passages in the lungs within a few minutes. VENTOLIN:

- helps to open up the airways in your lungs, making it easier for you to breathe.
- helps to relieve chest tightness, wheezing and cough associated with asthma.

VENTOLIN is used to treat breathing problems in people with asthma and similar conditions. Its effect includes relieving and preventing asthma symptoms brought on by exercise or other "triggers" Common triggers include house dust, pollen, cats, dogs and cigarette smoke.

If your asthma worsens (for example you have frequent symptoms or flare ups such as breathlessness, cough, wheezing, tight chest, night-time awakening or limited physical

ability), you should tell your doctor who may start or increase a medicine to control your asthma such as an inhaled corticosteroid (*see section 3*).

VENTOLIN contains a propellant called HFA 134a. This is less harmful to the environment than older inhalers. Older inhalers may taste differently to VENTOLIN. This will make no difference to how your medicine works.

## **2. Before you use VENTOLIN INHALER CFC-FREE**

### **Don't use VENTOLIN INHALER CFC-FREE**

- if you are allergic (hypersensitive) to salbutamol sulfate or any of the other ingredients of VENTOLIN.

If you think any of these apply to you, **don't use VENTOLIN INHALER CFC-FREE** until you have checked with your doctor.

### **Take special care with VENTOLIN INHALER CFC-FREE**

Before you use VENTOLIN your doctor needs to know if you:

- have **high blood pressure**
- have an **overactive thyroid gland**
- have a history of heart problems such as an irregular or fast heartbeat or angina (chest pain)
- have low levels of potassium in your blood
- are taking xanthine derivatives (such as theophylline) or steroids to treat asthma
- are taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition

Your doctor will monitor your potassium levels if you are taking any of the medicines listed here.

**Check with your doctor** if you think any of these may apply to you.

If your VENTOLIN fails to give relief for at least 3 hours, check with your doctor.

### **Other medicines and VENTOLIN INHALER CFC-FREE**

**Tell your doctor or pharmacist if you're taking any other medicines**, if you've taken any recently, or if you start taking new ones. This includes medicines bought without a prescription.

Some medicines may affect how VENTOLIN works, or make it more likely that you'll have side effects. These include:

- Beta-blockers (such as metoprolol) used to treat high blood pressure or a heart condition

**Your doctor or pharmacist** will decide if you should take VENTOLIN with these medicines.

### **Pregnancy and breast-feeding**

VENTOLIN is not usually recommended for use during pregnancy. If you are **pregnant**, or **think you could be**, or if you are **planning to become pregnant**, **don't take VENTOLIN** without checking with your doctor. **Your doctor** will consider the benefit to you and the risk to your baby of taking VENTOLIN while you're pregnant.

**It is not known** whether the ingredients of VENTOLIN can pass into breast milk. **If you are breast-feeding, you must check with your doctor** before you take VENTOLIN.

## **3. How to use VENTOLIN INHALER CFC-FREE**

### **How much to take**

VENTOLIN INHALER CFC-FREE should be used as required rather than regularly. If you are using VENTOLIN INHALER CFC-FREE more than twice a week to treat your asthma symptoms, not including preventive use before exercise or other triggers, this indicates poorly controlled asthma and may increase the risk of severe asthma attacks (worsening of asthma). You should contact your doctor as soon as possible to review your asthma treatment.

If you use your asthma anti-inflammatory medicine daily, e.g., "inhaled corticosteroid", it is important to continue using it regularly, even if you feel better.

**Always use your VENTOLIN INHALER CFC-FREE exactly as your doctor has told you.** You should check with your doctor, nurse or pharmacist if you are not sure.

## Adults

- **to relieve asthma symptoms/ attack** - The usual starting dose is one or two puffs (100-200 micrograms once a day)
  - **to prevent asthma symptoms/ attack** – The usual starting dose is two puffs (200 micrograms) 10 to 15 minutes before exercise or exposure to a “trigger”
  - **for regular treatment** (along with regular asthma anti-inflammatory medicine - inhaled corticosteroid) - The usual starting dose is one or two puffs (100-200 micrograms once a day).
- ➔ The maximum dose is 800 micrograms (two puffs up to four times in a 24 hour period).

## Children

- **to relieve asthma symptoms/ attack** - The usual starting dose is one puff (100 micrograms) once a day. The dose may be increased to two puffs (200 micrograms) if required.
  - **to prevent asthma symptoms/ attack** - The usual starting dose is one puff (100 micrograms) 10 to 15 minutes before exercise or exposure to a “trigger”. The dose may be increased to two puffs (200 micrograms) if required.
  - **for regular treatment** (along with regular asthma anti-inflammatory medicine - inhaled corticosteroid) - The usual starting dose is one or two puffs (100-200 micrograms once a day).
- ➔ The maximum dose is 800 micrograms (two puffs up to four times in a 24 hour period).

Do not inhale more puffs or use your inhaler more often. Tell your doctor if your medicine does not seem to be working as well as usual as your asthma may be getting worse and you may need a different medicine.

Some people find it difficult to release a puff of medicine just after they start to breathe in. A spacer device (a specially designed plastic or metal tube that is fitted to an inhaler on one end, while the patient breathes normally on the other end) may help to overcome this problem. Your doctor, nurse or pharmacist will be able to advise you about this. For babies and young children the Babyhaler spacer device is available to help young children obtain the maximum benefit from their inhaler. Your doctor, nurse or pharmacist will be able to advise you about this.

### **Instructions for use**

- VENTOLIN produces a fine mist which you inhale through your mouth into your lungs. Your doctor, nurse or pharmacist should show you how to use your inhaler. If you are not sure, ask your doctor, nurse or pharmacist.

**Carefully follow the step-by-step instructions given in section 7.**

### **If you forget to use VENTOLIN INHALER CFC-FREE**

**Don't take an extra dose to make up for a missed dose.**

Just take your next dose at the usual time. If you become wheezy or develop other symptoms of an asthma attack you may need to take your next dose earlier.

### **If you use too much VENTOLIN INHALER CFC-FREE**

If you use too much VENTOLIN, **contact your doctor or pharmacist for advice.** If possible, show them the VENTOLIN pack.

### **Don't stop VENTOLIN INHALER CFC-FREE without advice**

Take VENTOLIN for as long as your doctor recommends. Don't stop unless your doctor advises you to.

## **4. Possible side effects**

**If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.** If available, try a different fast-acting asthma medicine as soon as possible.

Like all medicines, VENTOLIN can cause side effects, although not everybody gets them.

### **Conditions you need to look out for**

**Allergic reactions:** These are very rare in people taking VENTOLIN. Signs include:

- skin rash (*hives*) or redness
- swelling, sometimes of the face or mouth (*angioedema*)
- becoming very wheezy, coughing or having difficulty in breathing
- suddenly feeling weak or light headed (may lead to collapse or loss of consciousness)

**Contact a doctor immediately** if you get any of these symptoms. **Stop taking VENTOLIN INHALER CFC-FREE.**

#### **Common side effects**

These may affect **up to 1 in 10** people:

- feeling shaky
- headache
- heart beating faster.

#### **Uncommon side effects**

These may affect **up to 1 in 100** people:

- irregular heart beat (palpitations)
- mouth and throat irritation
- muscle cramps.

#### **Rare side effects**

These may affect **up to 1 in 1,000** people:

- a low level of potassium in your blood
- increased blood flow to your extremities (widening of the blood vessels).

#### **Very rare side effects**

These may affect **up to 1 in 10,000** people:

- allergic reactions
- feeling unusually active, such as restlessness and excitability.

➔ **Tell your doctor or pharmacist** if any of the side effects listed becomes **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

### **5. How to store VENTOLIN INHALER CFC-FREE**

Keep out of the reach and sight of children.

The storage conditions are detailed on the packaging.

Do not use VENTOLIN after the expiry date shown on the pack.

- Protect from frost and direct sunlight

- Replace the mouthpiece cover firmly and snap it into position
- If the inhaler gets very cold, take the metal canister out of the plastic case and warm it in your hands for a few minutes before use. Never use anything else to warm it up.
- The metal canister is pressurised. Do not expose to temperatures higher than 50°C. Do not puncture, break or burn it even when apparently empty.

Don't dispose of medicine in wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

## **6. Further information**

### **What VENTOLIN INHALER CFC-FREE contains**

The active substance is salbutamol sulfate.

Each pressurised metered-dose VENTOLIN contains 200 doses of 100 micrograms of salbutamol (as salbutamol sulfate)

The other ingredients are:

1,1,1,2-tetrafluoroethane (also known as HFA 134a or norflurane)

### **What VENTOLIN INHALER CFC-FREE looks like and contents of the pack**

The medicine is a white to off-white suspension contained in an aluminium alloy can, sealed with a metering valve. Describe the device in detail: Each canister is fitted with a plastic actuator incorporating an atomising nozzle and fitted with a dustcap. VENTOLIN delivers 100 micrograms of salbutamol (as sulphate) per actuation.

Each canister contains at least 200 actuations.

### **Name and address of the holder of the certificate of registration**

GlaxoSmithKline South Africa (Pty) Ltd

57 Sloan Street

Bryanston, 2021

South Africa

### **Registration details**

Botswana:

Reg. No. B9303875 S2

Malawi:

Ref. No. PMPB/PL270/53 POM

Namibia:

Reg. No. 04/10.2.1/0911 NS1

Zambia:

Ref. No. 179/038 POM

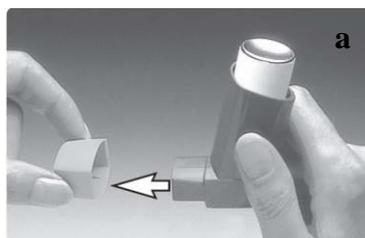
## 7. Step-by-step instructions

This section includes the following information:

- ❖ **Testing the inhaler**
- ❖ **Using the inhaler**
- ❖ **Cleaning the inhaler**

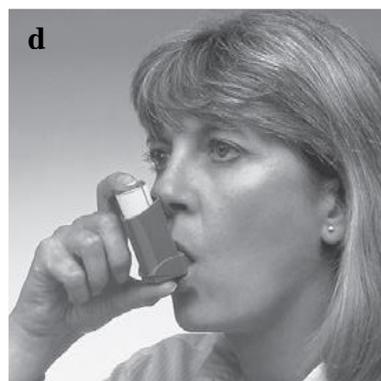
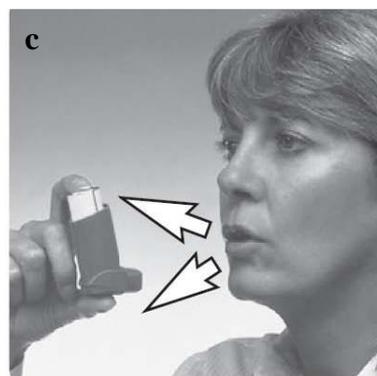
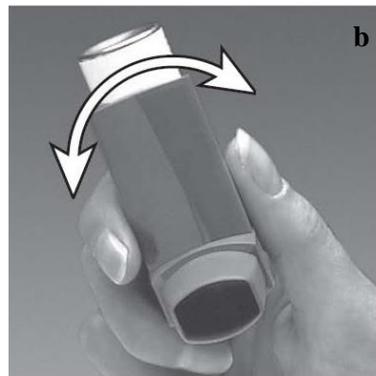
### Testing the inhaler

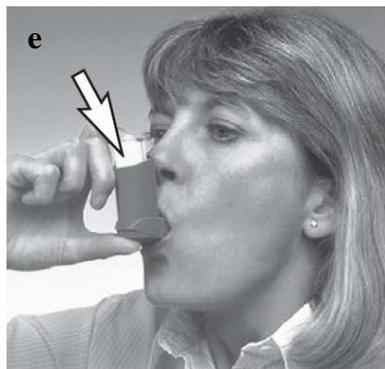
- Before using the inhaler for the first time, test that it is working
- Remove the mouthpiece cover by gently squeezing the sides of the cover (**picture a**)
- To make sure it works for the first time, shake it well, point the mouthpiece away from you and press the canister to release two puffs into the air.
- If it hasn't been used for 5 days or more, shake it well and release 2 puffs into the air to make sure it works.



### Using the inhaler

1. Remove the mouthpiece cover by gently squeezing the sides of the cover (**picture a**)
2. Check inside and outside of the inhaler including the mouthpiece for any 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 (**picture b**)
4. Hold the inhaler upright with your finger and thumb on the base, below the mouthpiece (**picture c**)
5. Breathe out as far as is comfortable (**picture c**) and then place the mouthpiece in your mouth between your teeth and close your lips around it but do not bite it (**picture d**)
6. Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine while still breathing in steadily and deeply (**picture e**)
7. Hold your breath and take the inhaler from your mouth. Continue holding your breath a few seconds or as long as is comfortable (**picture f**)
8. If your doctor has told you to take two puffs, wait about half a minute before you take another puff by repeating steps 3 to 7
9. Replace the mouthpiece cover by firmly pushing and snapping the cap into position.



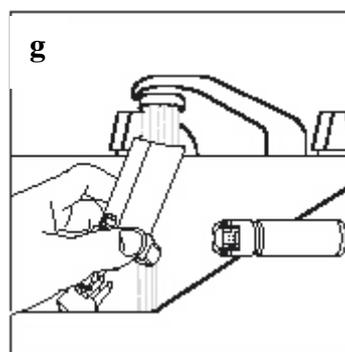


Practise in front of a mirror for the first few times. If you see a 'mist' coming from the top of your inhaler or the sides of your mouth you should start again from **step 2**. Young children may need help and their parents may need to operate the inhaler for them. Encourage the child to breathe out and operate the inhaler just after the child starts to breathe in. Practise the technique together. You may find the Volumatic spacer device, with a face mask, or the Babyhaler device useful if you have to give VENTOLIN to a baby or a child - speak to your doctor if you think you might need one of these. Older children or people with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece. If this does not help, a special device that acts as a lever aid for use called a Haleraid may make it easier. Your doctor, nurse or pharmacist will be able to advise you.

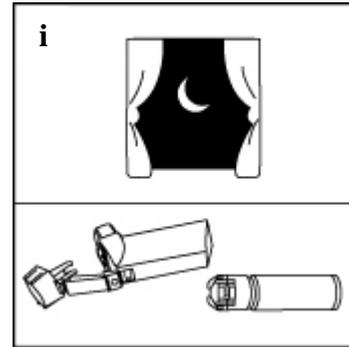
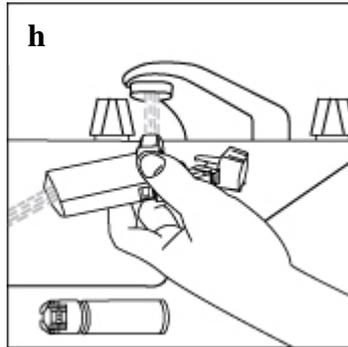
### Cleaning the inhaler

To stop your inhaler blocking, your inhaler should be cleaned at least once a week. To clean your inhaler:

- Remove the metal canister from the plastic casing of the inhaler and remove the mouthpiece cover
- Rinse the plastic casing thoroughly under warm running water (**picture g**) and then wash the plastic casing again through the mouthpiece (**picture h**)
- Dry the plastic casing **thoroughly** inside and out (such as overnight) (**picture i**)
- Replace the metal canister and mouthpiece cover.



**Do not put the metal canister into water.**



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