

# VENTOLIN CFC-FREE INHALER

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## **Consumer Medicine Information (CMI) summary**

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### **1. Why am I using VENTOLIN INHALER?**

VENTOLIN INHALER contains the active ingredient salbutamol sulfate. VENTOLIN INHALER, which you may know better as a 'puffer', helps you to breathe more easily.

For more information, see Section [1. Why am I using VENTOLIN INHALER?](#) in the full CMI.

### **2. What should I know before I use VENTOLIN INHALER?**

Do not use if you have ever had an allergic reaction to salbutamol sulfate or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use VENTOLIN INHALER?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with VENTOLIN INHALER and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use VENTOLIN INHALER?

- For adults, the usual dose is one or two puffs, as required, repeated four hourly.
- For children, the usual dose is one puff, repeated four hourly. The dose may be increased to two puffs, repeated four hourly, if required.
- More instructions can be found in Section [4. How do I use VENTOLIN INHALER?](#) in the full CMI.

### 5. What should I know while using VENTOLIN INHALER?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any Healthcare Professional (HCP) you visit that you are using VENTOLIN INHALER.</li><li>• Contact your doctor if you become concerned about any side effects.</li></ul>
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	<ul style="list-style-type: none"> <li>• Tell your doctor immediately, if you become or intend to become pregnant while using VENTOLIN INHALER and stop using it immediately.</li> <li>• Your doctor may tell you to take extra puffs of VENTOLIN INHALER if your wheezing or breathing suddenly gets worse. If you take extra puffs and do not get relief, tell your doctor immediately.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not take any other medicines to help you breathe without checking with your doctor.</li> <li>• You should not give this medicine to anyone else, even if their symptoms seem similar to yours.</li> <li>• Do not use VENTOLIN INHALER after the expiry date.</li> </ul>

<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store VENTOLIN INHALER below 30°C.</li> <li>• Clean VENTOLIN INHALER at least once a week.</li> <li>• Do not put the metal canister in water.</li> <li>• Do not put it in the refrigerator.</li> <li>• Do not expose to temperatures higher than 50°C.</li> <li>• Do not burn it or puncture it, even when it is empty.</li> </ul>
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For more information, see Section [5. What should I know while using VENTOLIN INHALER?](#) in the full CMI.

## 6. Are there any side effects?

Less serious side effects include headache, tremor (shakiness), feelings of anxiety, restlessness, or excitability, 'warm' feeling or flushing, restlessness in children, mouth or throat irritation and muscle cramps. Serious side effects include allergic reactions, irregular or fast heartbeat, increased blood flow to extremities, immediate breathing difficulties and wheezing, changes in blood potassium levels and lactic acidosis.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# VENTOLIN CFC-FREE INHALER

**Active ingredient:** *salbutamol sulfate 100 micrograms per inhalation*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using VENTOLIN INHALER. **You should also speak to your Healthcare Professional (HCP) if you would like further information or if you have any concerns or questions about using VENTOLIN INHALER.**

**Where to find information in this leaflet:**

- [1. Why am I using VENTOLIN INHALER?](#)
- [2. What should I know before I use VENTOLIN INHALER?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use VENTOLIN INHALER?](#)
- [5. What should I know while using VENTOLIN INHALER?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using VENTOLIN INHALER?

**VENTOLIN INHALER contains the active ingredient salbutamol sulfate.** VENTOLIN INHALER belongs to a group of medicines called bronchodilators. Because VENTOLIN INHALER gives fast relief from your chest symptoms, it is often called a 'reliever'.

**VENTOLIN INHALER is used for the relief of bronchospasm in patients with asthma or chronic obstructive pulmonary disease (COPD), and for relief against exercise-induced asthma and other stimuli known to induce bronchospasm.**

Bronchodilators relax the muscles of the small air passages in the lungs within a few minutes. This helps to open the airways and makes it easier for air to get in and out of the lungs. When it is used regularly, it helps the small air passages to remain open.

There are other types of medicines that prevent wheezing or chest tightness. These medicines are called 'preventers' and must be used every day. Your doctor may tell you to use a 'preventer' in addition to VENTOLIN INHALER.

**Ask your doctor if you have any questions about why you are using this medicine.**

## **2. What should I know before I use VENTOLIN INHALER?**

### **Warnings**

VENTOLIN INHALER contains enough medicine for 200 puffs only (whether inhaled and/or released into the air for testing) and it contains a propellant gas to deliver the medicine. However, after 200 puffs, your inhaler can continue to spray the gas but without the right dose of salbutamol, so you cannot be sure you will receive any medicine after using 200 puffs.

The inhaler does not have a dose counter.

Methods of telling that the inhaler is empty like shaking it, weighing it, or floating it in water, are not reliable. You should consider recording the number of puffs used.

Consider keeping a back-up inhaler.

If you are using more than one inhaler, it is recommended to keep track of the number of puffs for each inhaler separately.

### **Do not use VENTOLIN INHALER if:**

- you are allergic (hypersensitive) to salbutamol sulfate, or any of the ingredients listed at the end of this leaflet.
- the expiry date (EXP) printed on the pack has passed or if the packaging is torn or shows signs of tampering.

Do not use VENTOLIN INHALER to stop a miscarriage or premature labour.

Always check the ingredients to make sure you can use this medicine.

### **Check with your doctor or pharmacist if you:**

- have any other medical conditions.
- take any medicines for any other condition.
- have had to stop taking this or any other asthma medicine for any reason.
- are allergic to any medicine.
- have been diagnosed with, or are being treated for, a thyroid problem.



- have been diagnosed with, or are being treated for, high blood pressure.
- have been diagnosed with, or are being treated for, a heart problem.
- have been diagnosed with, or are being treated for, a liver problem.
- have been diagnosed with, or are being treated for, a kidney problem.
- have ever been told you have diabetes or high blood sugar.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

VENTOLIN INHALER is not usually recommended for use during pregnancy. Your doctor will weigh up the benefits to you against the potential risks to your baby when considering the use of VENTOLIN INHALER during your pregnancy.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

It is not known whether the ingredients of VENTOLIN INHALER can pass into breast milk.

### **3. What if I am taking other medicines?**

Tell your Healthcare Professional (HCP) if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with VENTOLIN INHALER and affect how it works or make it more likely that you will have side effects.**

**These medicines include:**

- xanthine derivatives (such as theophylline) or steroids to treat asthma.
- diuretics (also called water tablets), sometimes used to treat high blood pressure or a heart condition.
- beta-blockers used to treat high blood pressure or a heart condition.

**Check with your Healthcare Professional (HCP) if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VENTOLIN INHALER.**

### **4. How do I use VENTOLIN INHALER?**

#### **How much to use**

Always use VENTOLIN INHALER exactly as your Healthcare Professional (HCP) has told you to. Check with your HCP if you are not sure.

## **Adults:**

- To relieve asthma symptoms/attack, the usual dose for adults is one or two inhalations repeated four hourly.
- To prevent asthma symptoms/attack, the usual dose for adults is two puffs 10 to 15 minutes before exercise or exposure to a "trigger".
- Your doctor may tell you to take extra puffs of VENTOLIN INHALER if your chest condition suddenly gets worse. If you take extra puffs and do not get relief, tell your doctor immediately.
- Initial doses in the elderly may be lower than the recommended adult dose.

## **Children:**

- To relieve asthma symptoms/attack, the usual dose for children is one inhalation, as required, repeated four hourly, or as directed by their Healthcare Professional (HCP). The dose may be increased to two inhalations if required.
- To prevent asthma symptoms/attack, the usual dose for children is one inhalation 10 to 15 minutes before exercise or exposure to a "trigger". The dose may be increased to two inhalations if required.

## **How to use VENTOLIN INHALER**

- If VENTOLIN INHALER is new and you have not used it before, release four puffs into the air to make sure it works.
- If you have not used it for 5 days or more, or, if you drop the inhaler, you should shake it well, point the

mouthpiece away from you and release two puffs into the air before use to make sure that it works.

- This inhaler does not have a dose counter. You should consider recording the number of puffs that you are taking. If you are using more than one inhaler, it is recommended to keep track of the number of doses for each inhaler separately.

## **Using your inhaler:**

Follow the instructions on how to use VENTOLIN INHALER in the leaflet provided in the carton.

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 top of the inhaler to release salbutamol 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 3 to 7.
9. Replace the mouthpiece cover by firmly pushing and snapping the cap into position.

## **How to clean VENTOLIN INHALER:**

VENTOLIN INHALER should be cleaned at least once a week. You may not see any medicine build-up on the inhaler, but it is important to keep it clean so medicine build-up will not block the spray.

1. Remove the metal canister from the plastic casing (actuator) of the inhaler and remove the mouthpiece cover.
2. Rinse the actuator thoroughly under warm running water.
3. Turn the actuator upside down and rinse again through the mouthpiece thoroughly under warm running water.
4. Shake off as much water from the actuator as you can. Look into the mouthpiece to make sure any medicine build-up has been completely washed away. If there is any build-up, repeat Step 2 and Step 3.
5. Dry the actuator thoroughly inside and out (such as overnight).
6. Replace the metal canister and the mouthpiece cover.

**DO NOT put the metal canister in water.**

## **If you forget to use VENTOLIN INHALER**

VENTOLIN INHALER should be used as required. If you forget to take a dose, do not worry. Just take the next dose at the normal time or earlier if you become wheezy or feel tight in the chest.

**Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting unwanted side effects.**

- If you are not sure what to do, ask your Healthcare Professional (HCP).
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

## **If you use too much VENTOLIN INHALER (overdose)**

If you think that you have used too much VENTOLIN INHALER, you may need urgent medical attention. You may notice that your heart is beating faster than usual, you feel shaky or have a headache.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using VENTOLIN INHALER?**

### **Things you should do**

- Remind any Healthcare Professional (HCP) you visit that you are using VENTOLIN INHALER, especially if you are about to be started on any new medicine.
- Keep all of your doctor's appointments so that your progress can be checked.
- Visit your Healthcare Professional (HCP) regularly to check that you are using VENTOLIN INHALER in the right way. If you are not breathing the medicine in correctly, the medicine may not be helping you as much as it could.
- Talk to your Healthcare Professional (HCP) if you find it difficult to breathe in and press VENTOLIN INHALER at the same time. It may be better for you to use something called a spacer device with VENTOLIN INHALER. Your doctor or pharmacist will explain what this is and how to use it.
- If you change the make of the spacer you use this may alter the amount of drug delivered to the lungs. You should let your doctor know if your asthma symptoms worsen.
- 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.

## **Call your doctor straight away if you:**

- become pregnant while using this medicine.
- feel that your breathing suddenly becomes more difficult just after you have used VENTOLIN INHALER.
- feel that VENTOLIN INHALER does not help your breathing as much as usual.
- feel that the effect of VENTOLIN INHALER does not last as long as usual or lasts less than 3 hours.
- need more puffs of VENTOLIN INHALER to get relief.

Please see Section [6. Are there any side effects?](#) for more instances in which you should contact your doctor.

## **Things you should not do**

- VENTOLIN INHALER is only for you. You should not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use VENTOLIN INHALER to treat any other complaints unless your doctor tells you to.

## **Driving or using machines**

VENTOLIN INHALER is not expected to have any effect on your ability to drive or use machines.



## Action Plan

If you feel that VENTOLIN INHALER is not having the same effect as before, this may be a sign that your chest condition is getting worse. Your doctor may decide to add another medicine to your treatment.

## Looking after your medicine

- Straight after use, replace the mouthpiece cover firmly and click it into position.

Follow the instructions in the carton on how to take care of your medicine properly.

Store VENTOLIN INHALER in a cool dry place away from moisture, heat or sunlight where the temperature stays below 30°C. Keep VENTOLIN INHALER away from frost.

### **Do not store:**

- in the bathroom or near a sink, or
- in the car or on window sills, or
- in the refrigerator.

If VENTOLIN INHALER becomes very cold, it may not work properly. To warm it, pull the metal canister from its plastic holder and warm it in your hand for a few minutes. Do not warm the canister in any other way. Push the canister firmly back into its holder before using.

### **Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**WARNING:** The metal canister is pressurised. Do not expose to temperatures higher than 50°C. Do not burn it or puncture it, even when it is empty.

## **When to discard your medicine**

**You will find an expiry (or use by) date on the label of the metal canister. Do not use VENTOLIN INHALER after this date.**

You can recycle the plastic casing and cap of VENTOLIN INHALER with other plastic items.

The plastic casing (actuator) is manufactured from polypropylene.

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by the following list of side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

## Less serious side effects

Less serious side effects	What to do
<p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"><li>• headache</li><li>• tremor (shakiness)</li><li>• feelings of anxiety, restlessness or excitability</li><li>• 'warm' feeling or flushing</li><li>• restlessness in children</li></ul> <p><b>Respiratory, thoracic and mediastinal disorders:</b></p> <ul style="list-style-type: none"><li>• mouth or throat irritation</li></ul> <p><b>Musculoskeletal and connective tissue disorders:</b></p> <ul style="list-style-type: none"><li>• muscle cramps</li></ul>	<p><b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Allergic reactions:</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>● If you have any of the following symptoms after using VENTOLIN INHALER, stop using this medicine and tell your doctor immediately.</li> <li>● Symptoms of an allergic reaction usually include some or all of the following: <ul style="list-style-type: none"> <li>○ shortness of breath</li> <li>○ wheezing, coughing or difficulty breathing</li> <li>○ swelling of the face, lips/mouth, tongue, or throat</li> <li>○ rash, itching, redness or hives on the skin</li> <li>○ suddenly feeling weak or light-headed (may lead to loss of consciousness)</li> </ul> </li> </ul> <p><b>Cardiovascular disorders:</b></p> <ul style="list-style-type: none"> <li>● irregular or fast heartbeat</li> <li>● increased blood flow to extremities</li> </ul>	<p><b>Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<p><b>Immediate breathing difficulties and wheezing:</b></p> <ul style="list-style-type: none"> <li>• If your breathing or wheezing gets worse straight after using VENTOLIN INHALER, stop using it immediately, and tell your doctor as soon as possible.</li> </ul> <p><b>Metabolic and nutritional disorders:</b></p> <ul style="list-style-type: none"> <li>• Changes in blood potassium levels. This can only be detected when your doctor conducts tests over time to monitor your progress.</li> </ul> <p><b>Lactic acidosis:</b></p> <ul style="list-style-type: none"> <li>• This often affects people who have severe kidney disease.</li> <li>• Symptoms of lactic acidosis include some or all of the following: <ul style="list-style-type: none"> <li>◦ rapid breathing, shortness of breath</li> </ul> </li> </ul>	

Serious side effects	What to do
<p>even though there may be improvement in your wheezing</p> <ul style="list-style-type: none"> <li>◦ feeling cold</li> <li>◦ stomach pain, nausea and vomiting</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

## What VENTOLIN INHALER contains

<b>Active ingredient</b>	Salbutamol sulfate
<b>Other ingredients</b>	HFA-134a, a propellant
<b>Potential allergens</b>	VENTOLIN INHALER contains no other additives

**Do not take this medicine if you are allergic to any of these ingredients.**

Each puff contains 100 micrograms of salbutamol (as sulfate). There are 200 puffs in each VENTOLIN INHALER.

## What VENTOLIN INHALER looks like

VENTOLIN INHALER consists of a plastic casing which contains a small metal canister. The casing has a mouthpiece which is covered by a cap.

VENTOLIN INHALER (CFC-free) 100 micrograms per metered dose salbutamol, as sulfate. (AUST R 62695)

## Who distributes VENTOLIN INHALER

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

[www.gsk.com.au](http://www.gsk.com.au)

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