

# VENTOLIN NEBULES

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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 taking VENTOLIN NEBULES?

VENTOLIN NEBULES contains the active ingredient salbutamol sulfate. VENTOLIN NEBULES is used to help you to breathe more easily.

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

### 2. What should I know before I take VENTOLIN NEBULES?

Do not take if you have ever had an allergic reaction to VENTOLIN NEBULES 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. Do not use in children under 18 months.**

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

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

Some medicines may interfere with VENTOLIN NEBULES 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 take VENTOLIN NEBULES?**

- For adults, the usual dose is one 5 mg Nebule via nebuliser every 4-6 hours as necessary.
- For children (aged 4-12 years), the usual dose is one 2.5 mg Nebule via nebuliser every 4-6 hours as necessary.

More instructions can be found in Section [4. How do I take VENTOLIN NEBULES?](#) in the full CMI.

### **5. What should I know while taking VENTOLIN NEBULES?**

| <b>Things you should do</b> |                                                                                                                                            |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
|                             | <ul style="list-style-type: none"><li>• Remind any Healthcare Professional (HCP) you visit that you are taking VENTOLIN NEBULES.</li></ul> |

|                                 |                                                                                                                                                                                                                                                                                                                                                                                                                   |
|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                 | <ul style="list-style-type: none"> <li>• Contact your doctor if you become concerned about any side effects.</li> <li>• Tell your doctor immediately, if you become or intend to become pregnant while taking VENTOLIN NEBULES and stop using it immediately.</li> <li>• Tell your doctor if your breathing or wheezing gets worse straight after taking this medicine and stop taking it immediately.</li> </ul> |
| <b>Things you should not do</b> | <ul style="list-style-type: none"> <li>• Do not stop taking this medicine suddenly or change the dosage without checking with your doctor.</li> <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> </ul>                                                |

|                                    |                                                                                                                                                                                                                                                                                |
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| <b>Looking after your medicine</b> | <ul style="list-style-type: none"> <li>• Keep your Nebules in the pack until it is time to take them. Once the Nebules are removed from the foil overwrap, use within 3 months.</li> <li>• Store VENTOLIN NEBULES below 30°C away from moisture, heat, or sunlight.</li> </ul> |
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For more information, see Section [5. What should I know while using VENTOLIN NEBULES?](#) in the full CMI.

## 6. Are there any side effects?

Less serious side effects include headache, tremor, 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 NEBULES

**Active ingredient(s):** *salbutamol sulfate 2.5 milligrams or 5 milligrams in 2.5 millilitres per nebule.*

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## Consumer Medicine Information (CMI)

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

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

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

## 1. Why am I taking VENTOLIN NEBULES?

**VENTOLIN NEBULES contains the active ingredient salbutamol sulfate.** VENTOLIN NEBULES belong to a group of medicines called bronchodilators. Because

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VENTOLIN NEBULES gives fast relief from your chest symptoms, it is often called a 'reliever'.

**VENTOLIN NEBULES are 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. 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 NEBULES.

VENTOLIN NEBULES are not the only form of VENTOLIN available. Your doctor will decide which form of VENTOLIN is right for you.

Your doctor may have prescribed VENTOLIN NEBULES for another reason.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

## **2. What should I know before I take VENTOLIN NEBULES?**

### **Warnings**

#### **Do not take VENTOLIN NEBULES if:**

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

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

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

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

- have any other medical conditions.
- take any medicines for any other condition.
- are allergic (hypersensitive) to foods, dyes, preservatives or any other medicines.
- have had to stop taking this or any other asthma medicine for any reason.
- 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.

The ingredients of VENTOLIN NEBULES are known to cross the placenta during pregnancy. Your doctor can discuss with you the risks and benefits involved.

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

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

## **Children**

Do not give this medicine to children under 18 months.



### **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 NEBULES and affect how it works or make it more likely that you'll 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
- nebulised anticholinergics
- ephedrine or pseudoephedrine, to relieve a stuffy nose
- 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 NEBULES.**

## **4. How do I take VENTOLIN NEBULES?**

### **How much to take**

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

- Instructions provided by your HCP may differ from the information contained in this leaflet. The pharmacist's label will usually tell you how many VENTOLIN NEBULES should be taken.
- If your condition suddenly gets worse, your doctor may tell you to increase your dose.

VENTOLIN NEBULES should be used as required rather than regularly.

If you are using VENTOLIN NEBULES 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.

## **Adults:**

- The dose for adults is one 5 mg Nebule via the nebuliser every 4-6 hours as necessary.
- Initial doses in the elderly may be lower than the recommended adult dose.

## **Children (aged 4-12 years):**

- The dose for children (aged 4-12 years) is one 2.5 mg Nebule via the nebuliser every 4-6 hours as necessary.

## **When to take VENTOLIN NEBULES**

- Your doctor will decide how often and for how long you have to take VENTOLIN NEBULES.
- The pharmacist's label will usually tell you how often to take VENTOLIN NEBULES.
- VENTOLIN NEBULES should generally be taken every 4-6 hours as necessary.

## **How to take VENTOLIN NEBULES**

- VENTOLIN NEBULES must only be taken by inhalation from a nebuliser and must not be injected or swallowed.
- VENTOLIN NEBULES is a plastic container that contains a liquid. The liquid is put into a machine called a nebuliser. The nebuliser produces a fine mist which you breathe in through a face mask or

a mouthpiece. Make sure you know how to take it properly. If you have any problems ask your HCP.

- Do not let the liquid, or the mist produced by the nebuliser get into your eyes. You can wear glasses or goggles to protect them.
- Use your nebuliser in a well-ventilated room as some of the mist will be released into the air and may be breathed in by others.
- **Any solution remaining in the nebuliser should be discarded after use.**

## **If you forget to take VENTOLIN NEBULES**

VENTOLIN NEBULES should be taken 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 take too much VENTOLIN NEBULES (overdose)**

If you think that you have used too much VENTOLIN NEBULES, 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 in Australia**), 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 taking VENTOLIN NEBULES?**

### **Things you should do**

- Remind any Healthcare Professional (HCP) you visit that you are taking VENTOLIN NEBULES, especially if you are about to be started on any new medicine.
- If you are about to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
- If you are about to have any blood tests, inform your HCP that you are taking this medicine.

- Keep all of your doctor's appointments so that your progress can be checked.
- 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 taking this medicine.
- feel that VENTOLIN NEBULES do not help your breathing as much as usual.
- feel that the effect of VENTOLIN NEBULES does not last as long as usual.

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

### **Things you should not do**

- Do not stop using this medicine suddenly or change the dosage without medical advice.
- Do not take VENTOLIN NEBULES to treat any other complaints unless your doctor tells you to.
- VENTOLIN NEBULES is only for you. You should not give this medicine to anyone else, even if their symptoms seem similar to yours.

## **Driving or using machines**

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

## **Action Plan**

If you feel that VENTOLIN NEBULES are not having the same effect as before, this may be a sign that your chest condition is getting worse. Your doctor may decide to prescribe other forms of VENTOLIN, or another medicine, for you to use.

This medicine is only one part of a general plan to help you manage your asthma or other chest condition. You should discuss this plan with your doctor. Ask your doctor to check your treatment regularly.

## **Looking after your medicine**

- Store in the original pack until it is time to take your Nebules. If you take the Nebules out of the pack, they may not keep well.

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

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

### **Do not store:**

- in the bathroom or near a sink, or

- in the car or on window sills.

**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.

## **When to discard your medicine**

**Once the Nebules are removed from the foil overwrap, use within 3 months. Do not use VENTOLIN NEBULES after 3 months.**

## **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 about side effects.



## 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 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 NEBULES, 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 NEBULES, stop using it immediately, and tell your doctor as soon as possible.</li> <li>• If available, use a quick-acting asthma medicine 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> </ul> |            |

| Serious side effects                                                                                                                                                                                                                                                                                                                                     | What to do |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <ul style="list-style-type: none"> <li>• Symptoms of lactic acidosis include some or all of the following:               <ul style="list-style-type: none"> <li>◦ rapid breathing, shortness of breath even though there may be improvement in your wheezing</li> <li>◦ feeling cold</li> <li>◦ stomach pain, nausea and vomiting</li> </ul> </li> </ul> |            |

**Tell your doctor 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 before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What VENTOLIN NEBULES contains

|                            |                                                |
|----------------------------|------------------------------------------------|
| <b>Active ingredient</b>   | Salbutamol sulfate                             |
| <b>Other ingredients</b>   | Sodium chloride<br>Sulfuric acid<br>Water      |
| <b>Potential allergens</b> | VENTOLIN NEBULES do not contain a preservative |

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

### What VENTOLIN NEBULES looks like

VENTOLIN NEBULES are plastic containers that contain a liquid.

VENTOLIN NEBULES are supplied in packs of 20, arranged as four individually foil overwrapped pouches containing five Nebules linked together.

VENTOLIN NEBULES 2.5 mg / 2.5 mL (AUST R 12533): each 2.5 mL Nebule (0.1%) contains 2.5 mg of salbutamol (as salbutamol sulfate).

VENTOLIN NEBULES 5 mg / 2.5 mL (AUST R 12534):  
each 2.5 mL Nebule (0.2%) contains 5 mg of salbutamol  
(as salbutamol sulfate).

## **Who distributes VENTOLIN NEBULES**

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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