# **VENTOLIN INHALER, metered dose**

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

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

# 1. Why am I using VENTOLIN INHALER?

VENTOLIN INHALER contains the active ingredient salbutamol sulfate. VENTOLIN INHALER helps you to breathe more easily. For more information, see Section <u>1. Why am I using VENTOLIN INHALER?</u> 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 or two puffs, as required, repeated four hourly.

More instructions can be found in Section <u>4. How do I use VENTOLIN INHALER?</u> in the full CMI.

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

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist you visit that you are using VENTOLIN INHALER.</li> <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 using your VENTOLIN INHALER.</li> <li>Tell your doctor if your breathing or wheezing gets worse straight after using your VENTOLIN INHALER and stop using it immediately.</li> </ul>
Things you should not do	<ul> <li>Do not take any other medicines to help you breathe without checking with your doctor.</li> <li>Do not give this medicine to anyone else, even if their symptoms are similar to yours.</li> <li>Do not use your VENTOLIN INHALER if the expiry date has passed.</li> </ul>
Looking after your medicine	<ul> <li>Store VENTOLIN INHALER below 30°C.</li> <li>VENTOLIN INHALER should be cleaned 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> </ul>

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, shaky or tense feeling, 'warm' feeling, hyperactivity in children, mouth or throat irritation, muscle cramps and nausea. Serious side effects include an allergic reaction, irregular or fast heartbeat, immediate breathing difficulties and wheezing and changes in blood potassium levels.

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 INHALER, metered dose**

Active ingredient: salbutamol sulfate

# **Consumer Medicine Information (CMI)**

This leaflet provides important information about using VENTOLIN INHALER. You should also speak to your doctor or pharmacist 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 your VENTOLIN INHALER gives fast relief from your chest symptoms, it is often called a 'reliever'.

# VENTOLIN INHALER is used for the treatment or prevention of bronchospasm.

Fast-acting 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 your VENTOLIN INHALER.

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.

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, 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 control a miscarriage or premature labour.

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

### Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.
- have had to stop taking this medicine or any other asthma medicine for any reason.
- are allergic to any medicine, foods, dyes or preservatives.
- 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, or have had, a heart problem.
- have, or have had, a liver problem.
- have, or have had, a kidney problem.

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 <u>6. Are there any side effects</u>?

#### Pregnancy and breastfeeding

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

VENTOLIN INHALER is usually not 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 if you are breastfeeding or intend to breastfeed.

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

# 3. What if I am taking other medicines?

Tell your doctor or pharmacist 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.

### These medicines include:

- xanthine derivatives (such as theophylline) or steroids to treat asthma.
- water tablets (diuretics), 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 doctor or pharmacist 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 your VENTOLIN INHALER exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you are not sure.

- Follow the instructions on how to use your VENTOLIN INHALER in the leaflet provided in the carton.
- Do not exceed the recommended dosage.

VENTOLIN INHALER should be used as required rather than regularly.

If you are using VENTOLIN INHALER 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:

- 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 (200 micrograms) 10 to 15 minutes before exercise or exposure to a "trigger'.
- Your doctor may tell you to take extra puffs of your 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 (100 micrograms),

repeated four hourly. The dose may be increased to two inhalations (200 micrograms) if required.

 To prevent asthma symptoms/attack, the usual dose for children is one inhalation (100 micrograms) 10 to 15 minutes before exercise or exposure to a "trigger". The dose may be increased to two inhalations (200 micrograms) if required.

## How to use VENTOLIN INHALER

- If you are using your VENTOLIN INHALER for the first time, release two puffs into the air to make sure that it works.
- If you have not used it for 5 days or more, shake it well and release two puffs into the air to make sure that it works.
- Follow the instructions in the pack on how to use your VENTOLIN INHALER.
- The inhaler does not have a dose counter. You can consider recoding 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.

### How to clean VENTOLIN INHALER

VENTOLIN INHALER should be cleaned at least once a week.

- 1. Remove the metal canister from the plastic casing of the inhaler and remove the mouthpiece cover.
- 2. Rinse the actuator (the plastic casing) thoroughly under warm running water.
- 3. Dry the actuator thoroughly inside and out.
- 4. 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 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.

- If you are not sure what to do, ask your doctor or pharmacist.
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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

You should only take the number of puffs that you have been told.

If you think that you have used too much of your 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 0800 POISON or 0800 764 766), 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) that you visit that you are using VENTOLIN INHALER, especially if you are about to be started on any new medicine.
- Visit your doctor or pharmacist regularly to check that you are using your 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 doctor or pharmacist if you find it difficult to breathe in and use your VENTOLIN INHALER at the same time. It may be better for you to use something called a 'large volume spacer' with your VENTOLIN INHALER. Your doctor or pharmacist will explain to you what this is and how to use it.
- If you change the make of 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.

# 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 your VENTOLIN INHALER.
- feel that your VENTOLIN INHALER does not help your breathing as much as usual.
- feel that the effect of your VENTOLIN INHALER does not last as long as usual or lasts less than 3 hours.

# Things you should not do

- Do not take any other medicines to help you breathe without first checking with your doctor.
- Your 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 your 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 your 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. Do not use excessive force.
- You should always carry a spare inhaler.

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

Store it 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.

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

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

In very cold places, VENTOLIN INHALER may become very cold. To warm it, pull out the metal can from its plastic holder and warm it in your hand for a few minutes. Do not warm the can in any other way. Push the can firmly back into its holder before using.

## When to discard your medicine

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

You can recycle the plastic holder and cap of VENTOLIN INHALER with other plastic things.

GlaxoSmithKline inhalers are designed to give out a metered dose of medication until they are empty. You should keep a record of the number of doses you have used up. Floating the inhaler in water to estimate the amount of doses left in the inhaler is not recommended. Water may enter the valve in the inhaler, which may affect the accuracy of later doses. The humidity from the water may also encourage bacteria to grow in the valve.

## 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.

# 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.

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	
<ul> <li>Nervous system disorders:</li> <li>headache</li> <li>shaky or tense feeling</li> <li>'warm feeling' (caused by blood vessels expanding under the skin)</li> <li>hyperactivity in children</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.	
Respiratory, thoracic and mediastinal disorders: • mouth or throat irritation		
• Musculoskeletal and connective tissue disorders:		
muscle cramps		
Gastrointestinal disorders:		
• nausea		

## Serious side effects

Serious side effects	What to do
<ul> <li>Allergic reaction:</li> <li>If you have any of the following symptoms after using your 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> <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>	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
Cardiovascular disorders:	
<ul> <li>irregular or fast heartbeat</li> </ul>	
Immediate breathing difficulties and wheezing:	
If your breathing or wheezing gets worse straight after using your VENTOLIN INHALER, stop using it immediately, and tell your doctor as soon as possible.	
Metabolic and nutritional disorders:	
• This medicine may affect your blood potassium levels. Your doctor may do tests to check this.	

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 affects you experience, you can report side effects via <u>https://pophealth.my.site.com/carmreportsnz/s</u>

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 only available with a doctor's prescription.

## What VENTOLIN INHALER contains

Active ingredient	Salbutamol (as the sulfate)
(main ingredient)	
Other ingredients (inactive ingredients)	Non-CFC propellant HFA134a (also known as norflurane or 1,1,1,2-tetrafluoroethane)
Potential allergens	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 the 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 can. The casing has a mouthpiece which is covered by a cap.

Ventolin Aerosol inhaler, salbutamol sulfate metered dose 100 mcg/dose (200 actuations) (TT50-1525/12).

## Who distributes the VENTOLIN INHALER

GlaxoSmithKline NZ Ltd Private Bag 106600 Downtown Auckland 1143 New Zealand

Phone:(09) 367 2900Facsimile:(09) 367 2910

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