

Package leaflet: information for the user

Ventolin 100 Inhaler CFC-free, aerosol, suspension 100 micrograms/dose

salbutamol

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet:

1. What is Ventolin 100 Inhaler and what is this medicine used for?
2. When should you not use this medicine or be extra careful with it?
3. How do you use this medicine?
4. Possible side effects
5. How do you store this medicine?
6. Contents of the package and other information

1. What is Ventolin 100 Inhaler and what is this medicine used for?

Ventolin 100 inhaler contains the active ingredient salbutamol. Salbutamol belongs to a group of medicines called short-acting bronchodilators (effect lasts about 4 - 6 hours). Short-acting bronchodilators relax the muscles in the walls of the small air passages in the lungs within minutes. Ventolin 100 Inhaler:

helps to keep the airways in the lungs open, making it easier to breathe in and out
relieves the tight feeling in the chest and reduces wheezing and coughing associated with asthma

Ventolin 100 Inhaler is used to treat breathing problems in people with asthma and similar conditions. The effect also includes relief and prevention of asthma symptoms caused by exercise (exercise-induced asthma) and other factors that promote asthma. Other factors include house dust, pollen, cats, dogs, and cigarette smoke.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the substances in this medicine. You can find these substances in section 6 of this leaflet.

→ If you think this applies to you, do not use this medicine before consulting your doctor.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine. Before using this medicine, your doctor needs to know the following:

- if you have high blood pressure
- if you have an overactive thyroid
- if you have a history of heart problems such as an irregular or fast heartbeat or angina (chest pain)
- if you have low potassium levels in the blood
- or you are using xanthine derivatives (such as theophylline) or steroids for the treatment of asthma
- or you are using diuretics. These are sometimes used for the treatment of high blood pressure or other heart conditions

→ Your doctor will measure your potassium levels if you are using xanthine derivatives, steroids, or diuretics.

Ventolin 100 Inhaler should be used as needed rather than regularly.

If your asthma is active (you frequently have symptoms or flare-ups, such as shortness of breath that makes talking, eating, or sleeping difficult, coughing, wheezing, a feeling of tightness in the chest, or your physical ability is limited) inform your doctor immediately. Your doctor may advise you to start or increase the use of an asthma control medication, such as an inhaled corticosteroid.

Increasing use of a bronchodilator medication such as salbutamol may be a sign of worsening asthma. Inform your doctor as soon as possible if your medication does not seem to work as well as usual (for example, if you need more inhalations to relieve your breathing problems or if the use of your inhaler provides relief for less than 3 hours), as this may indicate that your respiratory symptoms are worsening and you may need another medication.

If you use Ventolin 100 Inhaler more than twice a week to treat your asthma symptoms, not counting use to prevent exercise-induced asthma, it is a sign that your asthma is not well controlled. This can increase the risk of severe asthma attacks (worsening of asthma) and these can have serious consequences and be life-threatening or even fatal. Contact your doctor as soon as possible to reassess your asthma treatment.

Do you use a daily medication for inflammation of your lungs, such as an 'inhaled corticosteroid'? Then it is important that you continue to use that medication regularly, even if you feel better.

Reports of tooth decay (caries) have been reported with the use of salbutamol. It is recommended to pay attention to good oral hygiene and regular dental check-ups, especially in children.

Are you using any other medications?

Are you using other medications in addition to Ventolin 100 Inhaler, have you recently done or are you maybe going to do this soon? Then tell your doctor or pharmacist.

Some medicines can affect the action of Ventolin 100 Inhaler, or make it more likely that you will get side effects. These include:

beta-blockers (such as propranolol, a group of medicines used to treat high blood pressure or a heart condition)

→ Your doctor or pharmacist will decide if you can use Ventolin 100 Inhaler with these medicines.

Pregnancy, breastfeeding and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine. Your doctor will determine if you can use Ventolin 100 Inhaler during pregnancy and breastfeeding.

Driving and using machines

It is unlikely that Ventolin 100 Inhaler affects the ability to drive and use machines.

3. How do you use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Ventolin 100 Inhaler is intended for inhalation use only, by inhaling through the mouth.

The recommended dosage is:

Adults and adolescents (12 years and older):

for relief of asthma - the usual starting dose is 1 to 2 inhalations (100-200 micrograms once per day)

The maximum dosage per day is 8 inhalations (800 micrograms maximum per day, if needed).

for prevention of exercise-induced asthma - 2 inhalations (200 micrograms) 10 to 15 minutes before exercise

Children (4 to 11 years):

for relief of asthma - the usual starting dose is 1 inhalation (100 micrograms) once a day. The dose can be increased to 2 inhalations (200 micrograms) if necessary. The maximum daily dose of 400 micrograms must not be exceeded to

prevent exercise-induced asthma - 1 inhalation (100 micrograms) up to 15 minutes before exercise prevention of exercise-induced asthma - 1 inhalation (100 micrograms) up to 15 minutes before exercise

if The maximum dose is 8 inhalations (800 micrograms) per 24 hours. Do not use more inhalations or use your inhaler more frequently. Tell your doctor if your medication does not seem to work as well as usual, as this may indicate that your respiratory symptoms are worsening and you may need a different medication.

For babies and young children under 4 years:

The starting dose is 1 inhalation

Ventolin 100 Inhaler via the Babyhaler spacer. If necessary As needed can take another inhalation after 5 minutes Ventolin 100 Inhaler can be administered via the Babyhaler spacer.

If you or your child finds it difficult to use the inhaler, the Volumatic spacer can be used. For babies and children under 4 years, there is a special spacer with a face mask available, namely the Babyhaler. Discuss this with your doctor, nurse, or pharmacist before you start using a Volumatic or Babyhaler spacer for the first time.

For further information on the use of the Volumatic spacer or the Babyhaler spacer, please refer to the instructions for use of these spacers.

Instructions for a correct use

Your doctor, nurse, or pharmacist should give you instructions on the correct use of your inhaler. They should regularly check how you use the inhaler. If you Ventolin 100 Inhaler not used as prescribed, this may mean that it does not or insufficiently helps for the condition for which Ventolin 100 Inhaler is prescribed. The medicine is contained in a metal canister under pressure. This canister is in a plastic holder with a mouthpiece (together with the inhaler). The inhaler produces a fine mist that must be inhaled into your lungs.

The testing of your inhaler

1. If you are using the inhaler for the first time, test if it works properly. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pulling off the cap.
2. To ensure it works properly, shake the inhaler well. Point the mouthpiece away from you and press the canister, releasing two puffs into the air. If you have not used your inhaler for 5 days or more, you should spray two puffs of medicine into the air before use.

The use of your inhaler

Before using your inhaler, it is important to start inhaling as slowly as possible.

1. Stand or sit up straight when you are going to use your inhaler.
2. Remove the mouthpiece cover (as shown in the first image). Check the inside and outside of the mouthpiece to ensure it is clean and free of foreign objects.
3. Shake the inhaler well to ensure that loose objects (such as coins, pieces of plastic, or dust that may be present in your bag or clothing) are removed and that the contents are evenly mixed.



4. Hold the inhaler upright, with the thumb on the base, behind the mouthpiece. Breathe well out as far as you can.



5. Place the mouthpiece in your mouth, between your teeth. Close your lips around it. Do not bite it.



6. Inhale through your mouth. Immediately after you start to inhale, press firmly on the top of the canister to spray a puff of medicine into your mouth while continuing to inhale steadily and deeply.



7. Hold your breath, remove the inhaler from your mouth, and take your finger off the top of the inhaler. Hold your breath for a few seconds or as long as you can without much effort.

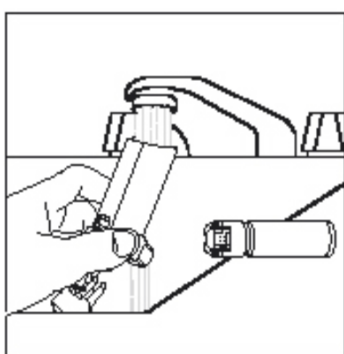


8. Wait about half a minute between administering each puff of medicine and then repeat steps 3 to 7 if your doctor has told you to take two puffs. Then wait half a minute before administering the next puff.
9. Always immediately replace the protective cap over the mouthpiece after use to keep it dust-free. If the cap is properly placed on the mouthpiece, it will click into place. If the cap does not click into place, turn the cap the other way and try again. Use not too much force.
10. Practice the first few times in front of a mirror. If you see 'mist' at the top of your inhaler or at the corners of your mouth, you must start again.

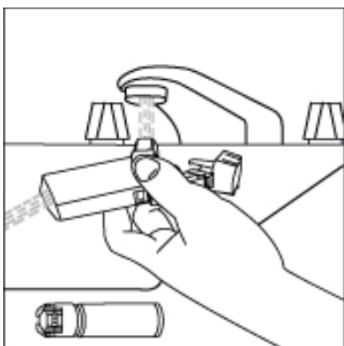
Cleaning your inhaler

To prevent your inhaler from blocking, it is important to clean it at least once a week. To clean your inhaler : Remove the metal canister from the plastic holder of the inhaler and remove the mouthpiece cover.:

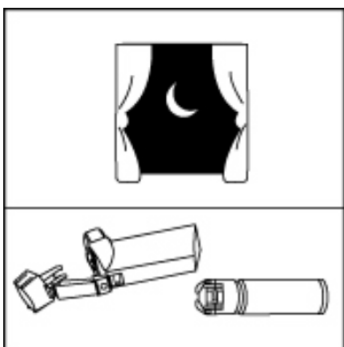
1. Dry the plastic holder thoroughly both inside and outside (for example, overnight) (see picture i)
2. Place the metal canister back into the plastic holder and the mouthpiece cover on the mouthpiece.
3. Do not place the metal canister in water.
4. Place the metal canister back into the plastic holder and the protective cap on the mouthpiece.



plaatje g



plaatje h



plaatje i

Do not place the metal spray can in water.

Have you used too much of this medicine?

If you have used too much of this medicine, contact your doctor or pharmacist for advice. If possible, take the Ventolin 100 Inhaler package with you.

Have you forgotten to use this medicine?

If you have forgotten to inhale your medicine, you should take the next dose at the prescribed time. Do not take a double dose to make up for a forgotten dose.

If you experience wheezing and breathlessness or other symptoms of an asthma attack, it may be necessary to take the next dose earlier.

If you stop using this medicine

Use this medicine as long as your doctor has prescribed. You may only stop using it on your doctor's advice.

Do you have any other questions about using this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

If your breathing worsens immediately after using the medicine (known as paradoxical bronchospasm), stop using it immediately and contact your doctor as soon as possible. If available, try another short-acting asthma medication as soon as possible.

Like any medicine, this medicine can also have side effects. Not everyone will experience them.

Circumstances in which you should be cautious

Allergic reactions: these are very rare in patients who Ventolin 100 Inhaler use.

Symptoms are:

- skin rash (hives) and redness
- swelling, sometimes of the face or mouth (angioedema)
- wheezing, shortness of breath, cough or breathing difficulties
- feeling suddenly weak or lightheaded. This can lead to fainting or loss of consciousness (collapse)

→ Contact your doctor immediately if you experience any of these symptoms. Stop using this medicine.

The following side effects have been reported with the use of Ventolin 100 Inhaler.

Common: occur in less than 1 in 10 patients:

- tremor (tremor)
- headache
- increased heart rate (tachycardia)

Sometimes: occur in less than 1 in 100 patients:

- irregular heartbeat (palpitations)
- cramp in the muscles
- irritation of mouth and throat

Rare: occur in less than 1 in 1,000 patients:

- deficiency of potassium in the blood (hypokalemia)
- increased blood flow to the limbs (arms, legs) due to dilation of the blood vessels (peripheral vasodilation)

Very rare: occur in less than 1 in 10,000 patients:

- hypersensitivity reactions (allergic reactions; see above)
- hyperactivity, such as restlessness and irritability
- arrhythmias

Unknown: cannot be determined from the available data:

- oxygen deficiency of the heart muscle (myocardial ischemia)
Although it is not exactly known how often it occurs, some people may occasionally feel pain in the chest area. This pain can be caused by heart problems. Inform your doctor (or if you are pregnant, your midwife) if you experience such symptoms while using salbutamol. Do not stop using salbutamol on your own, only do so if advised by your doctor.
- tooth decay (caries)

Reporting of side effects side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre, website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine., website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Keep out of the sight and reach of children.

Immediately after use, press the protective cap of the mouthpiece firmly and click it into position. Use no excessive force..

below 30 °C. 30 °C.

Do not store Ventolin 100 Inhaler in a cool place, as the inhaler may not work as well if it is cold.

Store Ventolin Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

Do not flush medications down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medications you no longer use. Proper disposal of medications ensures they are destroyed correctly and do not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is salbutamol. It is present in the form of salbutamol sulfate, equivalent to 100 micrograms of salbutamol.
- The other substance in this medicine is tetrafluoroethane (HFA 134a).

This medicine contains fluorinated greenhouse gases.

Each inhaler contains 18 g of HFC-134a (also referred to as tetrafluoroethane or HFA 134a). This is equivalent to 0.0257 tons of CO₂ (global warming potential GWP = 1,430).

What does Ventolin 100 Inhaler look like and what is in a package?

Ventolin 100 Inhaler is supplied in the metered-dose aerosol, which doses your medicine as a pressurized suspension for inhalation.

The aerosol can is pressurized and contains a white to off-white suspension for inhalation.

The inhaler is packaged in a cardboard box with 1 inhaler. The Ventolin 100 Inhaler is supplied in a package with at least 200 doses.

Marketing authorization holder and manufacturer

Marketing authorization holder

GlaxoSmithKline BV

Van Asch van Wijckstraat 55H

3811 LP Amersfoort

033 2081100

Manufacturer

Glaxo Wellcome SA

Avenida de Extremadura

09400 Aranda de Duero (Burgos)

Spain

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Ventolin 100 Inhaler CFC-free is registered in the Netherlands under number RVG 21440.

This leaflet was last approved in December 2024.

More information about this medicine can be found on the website of the Medicines Evaluation Board: www.cbg-meb.nl