

Salbutamol Ventolin 2.5 and 5.0 Nebules, inhalation solution 1 mg/ml and 2mg/ml

What are Ventolin Nebules and what is this medication used for?

The active ingredient in Ventolin Nebules is salbutamol. Salbutamol belongs to a group of medicines called short-acting bronchodilators (effects last for about 4-6 hours). Short-acting bronchodilators relax the muscles in the walls of the small air passages in the lungs within a few minutes. This medication:

- helps to keep the airways in the lungs open, making it easier for you to breathe
- relieves the tightness in the chest, and reduces wheezing and coughing associated with asthma

Ventolin Nebules are used in adults, adolescents, and children from 4 to 11 years of age with severe breathlessness caused by asthma or other chest conditions when other forms of treatment are not adequate. Ventolin Nebules are also prescribed for the treatment of severe asthma attacks. Ventolin Nebules should only be used for inhalation by means of a nebulizer. The solution should not be injected or taken orally.

When should you not use this medication or be extra careful with it?

When should you not use this medication?

If you are allergic to any of the substances in this medicine.

If you think this applies to you, do not use this medication until you have consulted your doctor about it.

When should you be extra careful with this medication?

Contact your doctor or pharmacist before using this medication. Before using this medication, your doctor needs to know the following: whether you have high blood pressure, whether you have an overactive thyroid, whether you have a history of heart problems such as irregular or fast heartbeat or angina (chest pain), whether you have low potassium levels in your blood, whether you use xanthine derivatives (such as theophylline) or steroids for the treatment of asthma, whether you use diuretics (water pills). These are sometimes used to treat high blood pressure or other heart conditions.

Your doctor will measure your potassium levels if you use xanthine derivatives, steroids or diuretics. Ask your doctor for advice if you think any of these points apply to you: you have diabetes, you use both nebulized anticholinergics (such as ipratropium bromide) and salbutamol.

Make sure the mist does not get into your eyes

If your asthma is active (you have frequent symptoms, exacerbations, or limited physical activity), tell your doctor. Your doctor may advise you to start or increase the use of an asthma control medication, such as an inhaled corticosteroid.

High doses of this medication can, in rare cases, cause lactic acidosis. To reduce the risk of problems, be aware of certain symptoms if you use this medication.

Children

The effectiveness of nebulized salbutamol in children under 18 months is unknown, and additional oxygen therapy may be necessary.

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 currently using any other medications besides Ventolin Nebules, or have you done so recently, or is it possible that you will use other medications in the near future? Tell your doctor or pharmacist. This also applies to medications you have purchased without a prescription.

Some medications may affect the effectiveness of Ventolin Nebules or make it more likely for you to experience side effects. These include:

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

Your doctor or pharmacist will decide whether you can use Ventolin Nebules with these medications.

Pregnancy, breastfeeding, and fertility

If you are pregnant, think you may be pregnant, planning to become pregnant, or breastfeeding, please contact your doctor or pharmacist before using this medicine. Your doctor will determine if you can use Ventolin Nebules during pregnancy and breastfeeding.

Driving and using machines

It is unlikely that the potential side effects of Ventolin Nebules will affect your ability to drive or operate machinery.

How to use this medicine?

Always use this medicine exactly as your doctor has told you. If you are unsure about the correct use, please contact your doctor or pharmacist.

- Ventolin Nebules should only be used for inhalation by means of a nebulizer. The solution should not be injected or taken orally.
- The nebulizer produces a fine mist that you inhale through a face mask or mouthpiece. It is important that you read the nebulizer instructions before using Ventolin Nebules. Make sure you know how to use the nebulizer or mouthpiece. If you have problems, ask your doctor or pharmacist for advice.
- Make sure that the nebulizer solution or mist produced by the nebulizer does not get into your eyes. To prevent this, you can use goggles or safety glasses.
- You must use the nebulizer in a well-ventilated room because otherwise any nebulized mist released may be inhaled by other people.

Your doctor, nurse, or pharmacist should show you how to use your medicine.

Follow the step-by-step instructions carefully.

The recommended dosage is: Use in adults and children (4 years and older)

- the usual starting dose is 2.5 mg
- this may be increased to 5 mg
- treatment may be given up to four times a day.

In children under 18 months, the efficacy of nebulized salbutamol is unknown, and additional oxygen therapy may be needed.

Step-By-Step Instructions

This section contains the following information: Using the Nebules, Diluting the Nebules, After using the Nebules, Using the Nebules

1. Your Nebules are in a foil package. Open the foil package only when you are ready to use the Nebule.
2. Open the foil package by tearing or cutting the foil at the top center.
3. Hold the Nebule strip in one hand and hold the last Nebule in the strip with the other hand.
4. Twist the Nebule away from you and downwards.
5. Put the remaining Nebules back in the foil package. Write the opening date on the foil package as a reminder. The expiration date is 3 months after opening the foil package. Put the opened foil package back in the box.
6. Hold the top of the Nebule that you just removed from the package. Twist the Nebule to open it.
7. Place the open end of the Nebule into the nebulizer and squeeze slowly. Make sure the entire contents are emptied into the nebulizer.
8. Assemble the nebulizer and use as directed.
9. Make sure the mist does not get into your eyes.

Diluting the Nebules

Do not dilute the contents of the Nebule unless your doctor has told you to do so.

1. If your doctor has told you to dilute the solution, empty the contents of the Nebule into the nebulizer.
2. Add the amount of sterile saline solution that your doctor has told you to use. Use only sterile saline solution for diluting the solution.
3. Close the nebulizer and gently shake the contents.

After using the Nebules

1. Use a new Nebule for each dose.
2. Only open a new Nebule when you are ready to use it. Any remaining liquid should be discarded. Do not store it for reuse.
3. Dispose of any remaining liquid from the nebulizer.
4. Clean the nebulizer as directed.
5. Do not flush medications down the toilet or sink, and do not throw them in the trash. Ask your pharmacist how to dispose of any leftover medications.

Did you use too much of this medicine?

If you have used too much of this medicine, please contact your doctor or pharmacist for advice. If possible, bring the Ventolin Nebule packaging with you.

Did you forget to use this medicine?

Do not take a double dose to make up for a missed dose. If you forget to inhale your medicine, take the next dose according to schedule. If you experience wheezing and shortness of breath or other symptoms of an asthma attack, you may need to take the next dose earlier.

If you stop using this medicine

Use this medicine as long as your doctor has prescribed it. You may only stop using it on the prescription of your doctor. Do you have any other questions about the use of this medicine? Please contact your doctor or pharmacist.

Possible side effects

If your breathing becomes worse immediately after using the medicine (known as paradoxical bronchospasm), stop using it immediately and contact your doctor as soon as possible. If available, try to use another short-acting asthma medicine. Like all medicines, this medicine can cause side effects, although not everyone gets them.

Conditions where you should be cautious: Allergic reactions: these occur very rarely in patients using this medicine. Symptoms include: skin rash/hives/redness (urticaria), swelling, sometimes of the face or mouth (angioedema), wheezing, breathing difficulties (bronchospasm), sudden weakness or lightheadedness. 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.

Lactic acidosis: an increase in the amount of lactic acid in the blood is a very rare side effect of this medicine. This usually affects people with severe kidney disease. Symptoms of lactic acidosis include: rapid breathing, shortness of breath even if your wheezing decreases, feeling cold, stomach pain, nausea, and vomiting. 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 Nebules:

Common, affecting less than 1 in 10 patients: tremor, headache, fast heartbeat (tachycardia)

Uncommon, affecting less than 1 in 100 patients: irregular heartbeat (palpitations), muscle cramps, mouth and throat irritation

Rare, affecting less than 1 in 1,000 patients: low potassium levels in the blood (hypokalemia) (see also section "Use with other medicines"), increased blood flow to the limbs (arms, legs) due to dilation of blood vessels (peripheral vasodilation)

If you experience a lot of any of the side effects or experience a side effect that is not listed in this leaflet, contact your doctor or pharmacist.

How do you store this medication?

Store below 30°C in the original packaging (to protect it from light). If the foil packaging has been opened, the Nebules are still usable for 3 months if stored in a dark place below 30°C. Once a Nebule has been opened, it must be used immediately.