Package Leaflet: Information for the User

Salbutamol 1mg/ml nebuliser solution
Salbutamol 2mg/ml nebuliser solution

salbutamol sulphate

The name of this medicine is Salbutamol 1mg/ml or 2mg/ml Nebuliser Solution, which will be referred to as Salbutamol Nebuliser Solution throughout this leaflet.

Read all of this 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.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Salbutamol Nebuliser Solution is and what it is used for
2. What you need to know before you use Salbutamol Nebuliser Solution
3. How to use Salbutamol Nebuliser Solution
4. Possible side effects
5. How to store Salbutamol Nebuliser Solution
6. Contents of the pack and other information

1. What Salbutamol Nebuliser Solution is and what it is used for

Salbutamol Nebuliser Solution is a liquid which, when used in a nebulising device, is converted into a mist which can then be inhaled. It contains the active ingredient salbutamol (salbutamol sulphate) which belongs to a group of medicines called fast-acting bronchodilator. These are used to make breathing easier by relaxing and opening up the airways in the lungs.

Salbutamol is used for the management of the symptoms of severe wheeziness or other chest conditions (such as asthma or bronchitis) particularly when no other treatment seem to work.

They are also used to treat severe attacks of asthma.

2. What you need to know before you use Salbutamol Nebuliser Solution

Do not use Salbutamol Nebuliser Solution if:

- you are allergic to salbutamol sulphate or any of the other ingredients of this medicine (listed in Section 6).
- you unexpectedly go into early labour (premature labour) or threatened abortion.

Warnings and precautions
Salbutamol nebuliser solution should be used as required rather than regularly.
Talk to your doctor, pharmacist or nurse before taking Salbutamol Nebuliser Solution if:

- your asthma is active (for example you have frequent symptoms or flare ups such as breathlessness that makes speaking, eating or sleeping difficult, cough, wheezing, tight chest or limited physical ability). Your doctor right away may start or increase a medicine to control

your asthma such as an inhaled corticosteroid.
- you are taking xanthine derivatives (such as theophylline) or steroids to treat asthma.
- you are taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition.
- you have taken other drugs used to relieve stuffy nose (such as ephedrine or pseudoephedrine) or other medicines used to treat asthma.
- you have high blood pressure
- you have a history of severe heart problems e. g. arrhythmia, severe heart failure
- you are diabetic
- you have an overactive thyroid
- use another nebuliser solution e.g. ipratropium bromide, make sure the mist does not get in your eyes. This can be prevented by using a mouthpiece instead of a face mask or goggles. If your breathing or wheezing gets worse or have chest pain straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.

This solution is for inhalation only and it should not be swallowed or used for injection.
You should tell your doctor if your asthma seems to be getting worse, or if this medicine stops working. You should not increase the dose without advice from your doctor.

Other medicines and Salbutamol Nebuliser Solution
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you go to hospital.

In particular tell your doctor, nurse or pharmacist if you are taking:
- other medicines for your asthma.
- beta blockers such as propranolol. These are not usually taken with salbutamol

Salbutamol Nebuliser Solution with food and drink
You can use salbutamol nebuliser solution at any time of day, with or without food.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before taking this medicine.

Driving and using machines
Salbutamol Nebuliser Solution is not likely to affect you being able to drive or use any tools or machines.

You should not drive or use machinery while using the nebuliser as this makes the mist for you to inhale.

3. How to use Salbutamol Nebuliser Solution

Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Using this medicine

- **do not inject or swallow the liquid.** Salbutamol Nebuliser Solution should only be inhaled using your nebuliser
- **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
- your doctor, nurse or pharmacist should show you how to use your medicine
- each small plastic container (Ampoule) contains some liquid
- the liquid is put into a nebuliser. This makes a fine mist for you to breathe in through a face mask

or mouthpiece
- 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.

Adults, adolescents aged 12 years and over and children 4 to 11 years of age
The usual starting dose is 2.5 mg up to 4 times a day, as described in "How to use your

Nebuliser". Your doctor may increase the dose to 5mg up to 4 times a day if required.

- Children under 18 years should only use a nebuliser to take reliever medications under the care of a doctor with expertise in the management of asthma so that deterioration in asthma control can be detected and treated without delay.

- Only use the nebuliser recommended by your doctor and supervise your child while they are using the nebuliser.

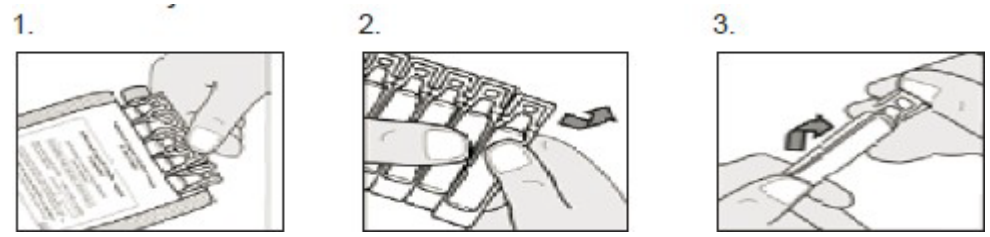
- Seek urgent medical assistance if the nebulised medication is not working, even if there is short-term recovery following use of prescribed nebulised medication.

Read and follow the instructions on the pharmacist's label. Do not take more doses than your doctor has prescribed or use your nebuliser more often then you are told. It is very important that you inhale each dose exactly as instructed.

If you need to take more inhalations than usual, or you find the dose is becoming less effective, or your asthma is getting worse tell your doctor or asthma nurse immediately as you may need other medicines.

If you need to go into hospital take your Salbutamol Nebuliser with you.

How to use your Salbutamol Nebuliser:



1. Set up the nebuliser and get it ready for filling.
2. Open the foil wrapping by cutting along the side. Only open when you are ready to use the first ampoule.
3. Take the ampoule strip out of the wrapping and remove the end ampoule by twisting downwards and away from you. Replace the unused ampoules back into the foil over-wrap and place them back into their box.
4. To open the ampoule. Hold the body and top of the ampoule securely and then twist the body.
5. Carefully place the open end of the ampoule into the nebuliser container and empty the contents by squeezing slowly.
6. Set up and use the nebuliser as you have been shown.
7. Ensure that any remaining solution left in your nebuliser after use is discarded and your nebuliser is cleaned as recommended.
8. Nebulisers should always be used in a well ventilated room.

Salbutamol Nebuliser Solution is intended to be used undiluted.
If you have been told by your doctor to dilute Salbutamol Nebuliser Solution, empty the contents of the ampoule into the nebuliser container, add the amount of sterile normal saline that your doctor has told you

to and shake gently to mix before using.

After use

- use a fresh ampoule for each dose. Only open a new one when you are ready to use it. If there is any liquid left over, throw it away. Do not save it to use again.

If you use more Salbutamol Nebuliser Solution than you should

If you use more than you should, talk to a doctor as soon as possible.

The following effects may happen:

- your heart beating faster than usual
- you feel shaky.
- hyperactivity

These effects usually wear off in a few hours.

If you forget to use your Salbutamol Nebuliser Solution

- If you forget a dose, take it as soon as you remember it.
- However, if it is time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop using Salbutamol Nebuliser Solution

Do not stop using salbutamol nebuliser solution without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If after using this medicine you immediately experience a worsening of your asthma symptoms or your wheezing gets worse then stop using this medicine and contact your doctor immediately.

If you get any of the following very rare side effects after taking this medicine you **should contact your doctor or hospital emergency department immediately:**

- **any sudden wheeziness, difficulty in breathing or dizziness**
- **swelling of the eyelids, face, lips or throat**
- **itching, raised bumps on the skin**
- **collapse i.e. fainting**

Talk to your doctor as soon as possible if:

- you feel your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while
- you may feel your heartbeat is uneven or it gives an extra beat
- these may affect up to 1 in 10 people.

If any of these happen to you, talk to your doctor as soon as possible. **Do not stop using this medicine unless told to do so.**

Tell your doctor if you have any of the following side effects which may have also been reported happen with this medicine:

Common (may affect up to 1 in 10 people)
- tremor
- headache

Uncommon (may affect up to 1 in 100 people)
- palpitations
- mouth and throat irritation
- muscle cramps

Rare (may affect up to 1 in 1,000 people)
- low blood potassium level in blood (feeling weak or may cause heart problems to people taking other drugs)
- increased blood flow to your extremities (peripheral dilatation).
- sleep disturbances

Very rare (may affect up to 1 in 10,000 people)
- hyperactivity
- low blood pressure
- restlessness or excitability
- irregular or rapid heartbeat
- difficulty in sleeping (insomnia)

Not known (frequency cannot be estimated from the available data):
- chest pain, especially if you have existing heart disease. Tell your doctor, nurse or pharmacist if this occurs. Do not stop using this medicine unless told to do so.
- build up of lactic acid in your blood, your doctor will know this from a blood test. This may cause stomach pain, hyperventilation, shortness of breath, even though there may be improvement in your wheezing cold feet and hands, irregular heartbeat and thirst.

If you think this medicine is not working well enough for you

If your medicine does not seem to be working as well as usual (for example you need higher doses to relieve your breathing problems or your inhaler fails to give relief for at least 3 hours), talk to your doctor as soon as possible. Your chest problem may be getting worse and you may need a different medicine. Do not take extra Salbutamol nebuliser solution unless your doctor tells you to.

If you use Salbutamol nebuliser solution more than twice a week to treat your asthma symptoms, not including preventive use before exercise, this indicates poorly controlled asthma and may increase the risk of severe asthma attacks (worsening of asthma) that can have serious complications and may be life-threatening or even fatal. You should contact your doctor as soon as possible to review your asthma treatment.

If you use a medicine against inflammation of your lungs daily, e.g., “inhaled corticosteroid”, it is important to continue using it regularly, even if you feel better.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Salbutamol Nebuliser Solution

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated carton and label after 'EXP'. The expiry date refers to the last day of that month.

Store in the original package to protect the ampoules from light. Always return the unopened ampoules to the foil over-wrap and place back into the box after use to protect from the light.

Use the ampoules within 3 months of first opening of the foil over-wrap.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Salbutamol Nebuliser Solution contains:

The active ingredient is salbutamol sulphate. Each ampoule contains 2.5mg or 5mg of salbutamol sulphate in 2.5mls of liquid

The other ingredients are sodium chloride, sulphuric acid (as a pH adjuster) and water.

What Salbutamol Nebuliser Solution looks like and the contents of the pack:

Salbutamol Nebuliser Solution is a liquid which when used in a nebulising device is converted into a mist to be inhaled.

The solutions are available in two strengths, 1mg per ml or 2mg per ml. Each pack contains 20 ampoules, and each ampoule contains 2.5ml of solution.

Salbutamol Nebuliser Solution comes in plastic polythene ampoules in strips of 5, with over wrap. Your medicine is available in boxes of 20 ampoules.

Marketing Authorisation Holder:

Cipla (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom.

Manufacturer:

Cipla (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom.

This leaflet was last revised on 11/2025.