

PACKAGE LEAFLET: INFORMATION FOR THE USER

Salbutamol 2.5mg/2.5ml and 5mg/2.5ml Nebuliser Solutions

or

Salbutamol 1mg/ml and 2mg/ml Nebuliser Solutions

[To be deleted as appropriate]

(Salbutamol)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Salbutamol Nebuliser Solution is and what it is used for
2. Before you take Salbutamol Nebuliser Solution
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4. Possible side effects
5. How to store Salbutamol Nebuliser Solution
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1 WHAT SALBUTAMOL NEBULISER SOLUTION IS AND WHAT IT IS USED FOR

Salbutamol belongs to a group of medicines called bronchodilators which help to open up the air passages in your lungs so that you can breathe more easily.

Salbutamol Nebuliser Solution helps to make breathing easier in patients who have long-standing breathing difficulties. It is also given to treat severe attacks of asthma.

2 BEFORE YOU TAKE SALBUTAMOL NEBULISER SOLUTION

Do not take Salbutamol Nebuliser Solution

- If you are allergic (hypersensitive) to salbutamol
- If you are allergic to any of the other ingredients (see section 6 Further Information)

Some forms of Salbutamol are used to help control premature labour. Salbutamol Nebuliser Solution is not to be used for this purpose

Take special care with Salbutamol Nebuliser Solution

Talk to your doctor if any of the following apply to you:

- if you have diabetes
- if you have a heart condition or have recently had a heart attack

- if you have high blood pressure
- if you have an overactive thyroid gland
- if you have a history of heart disease, irregular heartbeat/rhythm including a very fast pulse or angina
- if you have an aneurysm (a widening of the wall of a blood vessel)
- if you suffer from glaucoma (excessive pressure inside your eyes)
- if you have ever been told that you suffer from pheochromocytoma. This is a rare tumour which produces chemicals that can cause restlessness, high blood pressure, and your heart to beat faster.

Taking other medicines

Tell your doctor if you are taking any of the following as they may interact with Salbutamol Nebuliser Solution:

- steroids including prednisolone
- medicines called xanthines such as theophylline
- medicines called beta blockers, as these can reduce the effectiveness of your medicine
- diuretic medicines (commonly known as “water tablets” including non-sparing potassium diuretics such as furosemide and indapamide)
- digoxin, which is used in the treatment of heart failure
- tricyclic antidepressants (for depression)
- ipratropium bromide (for asthma)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant, think you are pregnant or are breast-feeding, you should not use Salbutamol Nebuliser Solution unless your doctor tells you to.

If you become pregnant whilst taking this medicine you should tell your doctor as soon as possible.

Driving and using machines

Salbutamol Nebuliser Solution has no known effects on the ability to drive and use machines.

3 HOW TO TAKE SALBUTAMOL NEBULISER SOLUTION

Always use Salbutamol Nebuliser Solution exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor may tell you to use your nebuliser at regular times every day or only when you are wheezy or short of breath. Allow 3-6 hours between doses. You should always follow your doctor’s instructions.

Adults and adolescents aged 12 years and over

- the usual starting dose is 2.5mg up to four times daily. Your doctor may increase this to 5mg up to four times daily.

Children aged 4 to 11 years

- the usual dose is 2.5mg to 5mg up to four times a day.

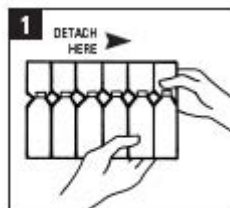
Other pharmaceuticals forms may be available that are more appropriate for children under 4 years old. The effect of Salbutamol Nebuliser Solution in infants under 18 months is uncertain. Please speak to your doctor for further information.

General instructions:

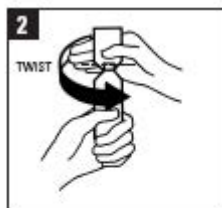
Your medicine should be used with a power operated nebuliser. The “mist” produced is then inhaled through a face mask or mouthpiece. Do not let the solution or the mist produced by the nebuliser get in your eyes.

Instructions for use:

1. Prepare your nebuliser following the manufacturer’s instructions and/or the dosing instructions given by your doctor.
2. Take a strip of ampoules from the foil sachet. Remove one or two ampoules (depending on your dose) [Diagram 1] and put the rest back in the foil sachet and replace the foil sachet in the carton. Never use an ampoule that has been opened already or if the solution is discoloured.
3. Hold the ampoule upright and open it by twisting off the top. [Diagram 2]



[Diagram 1]



[Diagram 2]

4. Unless otherwise instructed by your doctor, squeeze all of the liquid from the plastic ampoule into the nebuliser chamber
5. Throw away the empty plastic ampoule
6. If your doctor has told you to dilute the solution, this should be carried out using ONLY sterile sodium chloride 0.9% solution. Use the amount which your doctor has told you to use.
7. Turn on the nebuliser and breathe in the “mist” calmly and deeply using a face mask or mouthpiece. If you are using a face mask, make sure it is fitted correctly. Protect your eyes from the mist produced as it can cause pain or discomfort if it gets into them. This is especially important if you suffer from glaucoma.
8. The length of time it takes your nebuliser to turn your medicine into a mist will depend on the type of equipment you use. You will know when your treatment is complete because the fine mist will stop coming out of your mask or mouthpiece.
9. You must wash your nebuliser, face mask and/or mouthpiece in warm soapy water and rinse well after each use.

In most people, Salbutamol Nebuliser Solution will start to give relief from wheezing and chest tightness within about 5 minutes and the effects should last for about 4-6 hours.

After using your nebuliser a few times you will know how long the effects normally last for you.

Contact your doctor immediately if:

- **You are not getting relief from your current dose or you are having to take more inhalations**
- **Your breathing is not improving or is getting worse**
- **Your chest feels tight**

These are signs that your condition is not being controlled and you may need different or additional treatment.

Your doctor may also prescribe a second type of nebuliser solution to use at the same time as this medicine. Follow your doctor's advice on how to use the nebuliser properly. If you are in any doubt, ask your doctor.

If you use more Salbutamol Nebuliser Solution than you should you may feel unwell and overtired, shaky, dizzy, have chest pains and feel that your heart is beating faster than usual. Call your doctor immediately or go to the nearest hospital casualty department. If you feel shaky you should not drive. Take this leaflet or an ampoule with you so the hospital will know what you have taken.

If you forget to use Salbutamol Nebuliser Solution, take the next dose when it is due or before you become wheezy. Do not take a double dose to make up for the one you missed.

If you stop using Salbutamol Nebuliser Solution this may make your condition worse. Do not stop taking your medicine unless your doctor tells you to do so.

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

4 POSSIBLE SIDE EFFECTS

Like all medicines, Salbutamol Nebuliser Solution can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor immediately if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face, lips or throat, or a rash or itching especially affecting the whole body.

Rarely, inhaled medicines such as salbutamol can cause acute wheezing and/or shortness of breath. If this occurs, stop using your medicine immediately and seek medical help.

The following side effects have also been reported:

Common side effects (probably affecting less than 1 person in 10):
restlessness, tremor (shaking), nausea, taste alteration (bad, unpleasant or unusual taste), sweating, dizziness, rash, hives, itching, redness of the skin, headache, mouth and throat irritation, burning sensation of the tongue.

Rare side effects (probably affecting less than 1 person in 1,000):
hyperactive behaviour, an awareness of your heartbeat, increase in heart rate, an irregular heart rhythm or chest pain, muscle cramp, increased blood flow or pain in the arms and legs.

Sometimes this medicine can cause a lowering of potassium levels in the blood which can make you feel generally unwell and over-tired. You may also experience frequent urination (passing water). If you notice any of these effects, tell your doctor who may arrange for you to have a blood test.

Very rare side effects (probably affecting less than 1 person in 10,000):
hyperexcitability, sleep disturbances, hallucinations, skin rashes, swelling of the face, lips, eyes and throat, feeling faint and collapsing.

Although it is not known exactly how often this happens, some people may occasionally experience chest pain (due to heart problems such as angina). Tell your doctor/midwife if you develop these symptoms whilst receiving treatment with salbutamol, but do not stop using this medicine unless told to do so.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 HOW TO STORE SALBUTAMOL NEBULISER SOLUTION

Keep out of the reach and sight of children.
Store the product below 25°C. Store in the original package.

Do not use Salbutamol Nebuliser Solution after the expiry date which is stated on the carton and ampoule after Exp. The expiry date refers to the last day of that month.

Open one foil pack at a time and use all 10 ampoules before opening the next foil pack. Always replace the foil pack in the carton after use. When first opening a foil pack, note the date of opening and add 6 months to this date which will be the "Do not use after" date. Unused ampoules remaining in an opened foil pack after the "Do not use after" date should not be used, but should be returned to your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 FURTHER INFORMATION

What Salbutamol Nebuliser Solution contains

- The active substance is Salbutamol 2.5mg/2.5ml or 5mg/2.5ml (as salbutamol sulphate).
- The other ingredients are sodium chloride, water for injections and sulphuric acid.

What Salbutamol Nebuliser Solution looks like and contents of the pack

Salbutamol Nebuliser Solutions are clear, colourless to pale yellow solutions in clear plastic ampoules.

Salbutamol Nebuliser Solutions are packed in cartons containing 20 or 60 ampoules in foil wrapped strips of 10. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

UK

Breath Limited,
Unit 2, Eastman Way, Stevenage,
Hertfordshire, SG1 4SZ,
United Kingdom

Or

DK, NL, NO, SE
Arrow Generics Limited
Whiddon Valley, Barnstaple, Devon,
EX32 8NS
United Kingdom

Or

IE
Breath Limited,
Unit 2, Eastman Way, Stevenage,
Hertfordshire, SG14SZ,
United Kingdom

[To be deleted as appropriate]

Manufacturer:

Laboratoire Unither,
Espace Industriel Nord,
151 rue André Durouchez- CS 28028
80084 AMIENS Cedex 2,
France

This leaflet was last approved in {MM/YYYY}.