

PATIENT INFORMATION LEAFLET
SALBUTAMOL 1MG/ML AND 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 taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your 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 gets serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist. (Section 4)

In this leaflet

1. What Salbutamol Nebuliser Solution is and what it is used for
2. 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. Further 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 bronchodilators. 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. BEFORE YOU USE SALBUTAMOL NEBULISER SOLUTION

Do not use Salbutamol Nebuliser Solution if you are:

- **allergic (hypersensitive)** to salbutamol, salbutamol sulphate, or any of the **other ingredients** in Salbutamol Nebuliser Solution (these are listed in section 6, Further Information)

- in **premature labour** or have a **threatened miscarriage**

Take special care with Salbutamol Nebuliser Solution if you:

- suffer from severe or unstable asthma:
 - your doctor should monitor you frequently, and you should be treated with additional drugs and not just salbutamol or other bronchodilating ('reliever') drugs
 - potentially serious low levels of potassium in the blood (hypokalaemia) have been reported when salbutamol is given, particularly when it is taken with other drugs such as xanthine derivatives and steroids (used in other asthma treatments), diuretics (water tablets) and laxatives
- use another nebuliser solution such as ipratropium bromide, you need to make sure the mist doesn't get in your eyes as it can aggravate glaucoma (a potentially serious and painful condition of the eyes)
- are being treated for an overactive thyroid, salbutamol may interfere with your thyroid medication
- are a diabetic
- if you have existing heart disease such as angina or heart failure you must seek immediate medical

- advice especially if you experience any chest pain or other symptoms of heart disease
- if you have been taking laxatives for a long time

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.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines including medicines obtained without a prescription. It is important that you tell your doctor if you are taking the following medicines, as they may decrease or increase the effect of Salbutamol Nebuliser Solution and vice versa.

- are taking any other beta-adrenergic agonists (these are medicines used to treat severe asthma and other lung conditions)
- beta blockers such as propranolol. These are not usually taken with salbutamol
- xanthine derivatives and steroids (used in other asthma treatments)
- diuretics (water tablets)
- laxatives.

Pregnancy and breast-feeding and fertility

Do not use Salbutamol Nebuliser Solution if you are in premature labour or have a threatened miscarriage.

Do not breast-feed unless your doctor advises you to as salbutamol passes into breast milk.

The safety of salbutamol during pregnancy has not been established. Tell your doctor if you are pregnant, likely to be pregnant or are trying to become pregnant.

There is no information on the effects of salbutamol on human fertility. There were no adverse effects on fertility in animals

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

It is unlikely that Salbutamol Nebuliser Solution will affect your ability to drive or use machines.

3. HOW TO USE SALBUTAMOL NEBULISER SOLUTION

This product is for inhalation use only. It should not be injected or swallowed.

Your doctor may tell you to use your nebuliser at a regular time each day or may tell you only to use it when you are very wheezy or short of breath.

Always use the nebuliser exactly as your doctor or asthma nurse has told you and use the recommended dose. Make sure that you know how to use your nebuliser properly. You should check with your doctor or pharmacist if you are not sure.

Adults, Elderly and Children aged over 18 months

The usual dose is 2.5mg to 5mg salbutamol used up to 4 times a day, as described in "How to use your Nebuliser".

For severe attacks in hospital a higher dose may be given.

Paediatric Population

Children aged 12 years and over: Dose as per adult population.

Children aged 4 to 11 years: 2.5mg to 5mg up to four times a day.

Other pharmaceutical forms may be more appropriate for administration in children under 4 years old.

Clinical efficacy of nebulised salbutamol in infants under 18 months is uncertain. As transient hypoxaemia may occur, supplemental oxygen therapy should be considered.

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 than 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.

If you use more Salbutamol Nebuliser Solution than you should

If you have accidentally taken more than the prescribed dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**. Remember to take your nebuliser with you.

You may develop a condition where you have low levels of potassium in your blood if you overdose with salbutamol

If you forget to use your Salbutamol Nebuliser

If you miss a dose do not worry. Just inhale the next dose when it is due or before if you become wheezy. Do not take a double dose to make up for a forgotten dose.

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 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

The following side effects have also been reported:

Common (seen in less than 1 in 10 people and more than 1 in 100 people)

- tremor
- headaches
- rapid heartbeat

Uncommon (seen in less than 1 in 100 people and more than 1 in 1000 people)

- palpitations
- mouth and throat irritation
- muscle cramps

Rare (seen in less than 1 in 1000 people and more than 1 in 10,000 people)

- low blood potassium level in blood (feeling weak or may cause heart problems to people taking other drugs)
- flushing

Very rare (occurring in less than 1 in 10,000 people)

- hyperactivity in children
- low blood pressure
- restlessness or excitability
- irregular or rapid heartbeat

The following side effects can also happen but the frequency of these is unknown:

- chest pain, especially if you have existing heart disease. See your doctor if this happens
- 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, cold feet and hands, irregular heartbeat and thirst.

Patients who are also taking anticholinergic medicines, (such as ipratropium) mixed with salbutamol in their nebulisers, may suffer from an eye condition called glaucoma (an increased pressure in the eyes), which can cause severe pain in the eye and damage to your vision. It is important to avoid getting the nebuliser mist in your eyes. This can be avoided by using a mouthpiece instead of a face mask or using protective eye goggles to prevent the mist from getting in the eyes if a face mask is preferred.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **United Kingdom Yellow Card Scheme**

Website: www.mhra.gov.uk/yellowcard

5. HOW TO STORE SALBUTAMOL NEBULISER SOLUTION

Keep out of the reach and sight of children.

Do not take this medicine after the expiry date (Exp.) stated. 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.

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 ingredient is salbutamol sulphate. Each nebule 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:

Fannin (UK) Limited, 42-46 Booth Drive, Park Farm South, Wellingborough,
Northamptonshire, NN8 6GT, UK

Manufacturer responsible for batch release:

Fannin (UK) Limited, 42-46 Booth Drive, Park Farm South, Wellingborough,
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