

Package leaflet: Information for the User

Salbutamol Neutec 2.5 mg nebuliser solution

salbutamol

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

1. What Salbutamol Neutec is and what it is used for

Salbutamol Neutec contains a medicine called salbutamol. This belongs to a group of medicines called short and fast-acting bronchodilators.

- Bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out.
- They help to relieve chest tightness, wheezing and cough.

Salbutamol Neutec is used to treat breathing problems in people with asthma and other lung conditions that cause narrowing of the airways (such as chronic obstructive pulmonary disease). They are usually given to people who suffer seriously from these conditions when other forms of treatment do not seem to work. Salbutamol Neutec can be used to treat adults, adolescents and children, aged 4 to 11 years.

Salbutamol Neutec is provided in a small plastic container that contains a liquid. The liquid is put into a machine called a nebuliser. This machine makes a fine mist for you to breathe in through a face mask.

2. What you need to know before you use Salbutamol Neutec

Do not use Salbutamol Neutec if:

- you are allergic to salbutamol sulphate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, nurse or pharmacist before taking Salbutamol Neutec if:

- you have high blood pressure
- you are diabetic
- you have an overactive thyroid gland
- you have a history of heart problems such as severe heart failure, an irregular or fast heartbeat or chest pain (angina pectoris)
- you use another nebuliser solution e.g. ipratropium bromide

- you suffer from acute severe asthma (your doctor may need to carry out blood tests to monitor the amount of potassium in your blood)

High doses of salbutamol can on rare occasions cause a condition known as lactic acidosis. You must look out for certain symptoms while you are taking Salbutamol Neutec, to reduce the risk of any problems. See possible side effects in section 4.

Use of salbutamol can sometimes cause lowering of potassium levels in the blood, particularly if you are taking certain other medicines at the same time. If you are at risk of this happening, your doctor might recommend further tests to monitor your blood more closely.

If you are using this medicine at home and you notice the medicine is not working as well as usual, do not increase the dose and do not use the medicine more often, but tell your doctor as soon as possible.

Make sure the mist does not get in your eyes. This can be prevented by using a mouthpiece instead of a face mask or using goggles.

If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately and tell your doctor as soon as possible.

Other medicines and Salbutamol Neutec

Tell your doctor, nurse or pharmacist 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:

- beta-blockers (medicines that are used for cardiac disease e.g. propranolol)
- other medicines for your asthma
- diuretics, corticosteroids and xanthine derivatives (such as theophylline)

Tell your doctor that you are taking Salbutamol Neutec if you are going to have an operation as it may interact with some anaesthetics.

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 for advice before taking this medicine.

Salbutamol Neutec can be used during pregnancy when considered necessary by your doctor.

Information on whether this medicine passes into breast milk is not sufficient to assess the risk to the child.

Driving and using machines

Salbutamol Neutec 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.

3. How to use Salbutamol Neutec

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

Salbutamol Neutec should be used as required rather than regularly.

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), you should tell your doctor right away who may start or increase a medicine to control your

asthma such as an inhaled corticosteroid.

Tell your doctor as soon as possible 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) as your asthma may be getting worse and you may need a different medicine.

If you use Salbutamol Neutec 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.

Using this medicine

- your doctor, nurse or pharmacist should show you how to use your medicine
- only use the nebuliser recommended by your doctor and supervise your child while they are using the nebuliser
- each single-dose container contains some liquid
- the liquid is put into a suitable 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
- you can use Salbutamol Neutec at any time of day, with or without food
- **do not inject or swallow the liquid.** This medicine 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.

The recommended dose for adults and children aged 4 and over is:

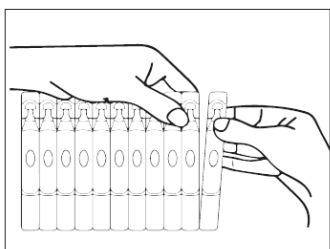
- The suitable dose is 2.5 mg up to four times daily.
- This may be increased to 5 mg up to four times daily, if required.
- The maximum dose is 5 mg, four times daily.

In adults, higher doses may be given for the treatment of severe airways obstruction, but only under the direction and supervision of a doctor in hospital.

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

Instructions for use

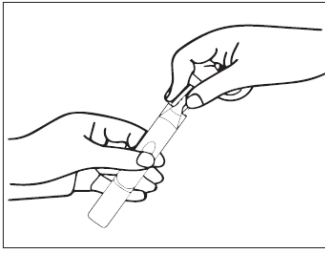
1. Your single-dose containers are in a foil pouch. Do not open the foil pouch pack until you need to use it.
2. Open the foil pouch and take out the strip of single-dose containers.
3. Hold the strip of single-dose containers in one hand, with your other hand hold the last single-dose container in the row.
4. Twist the single-dose container downwards and away from you.



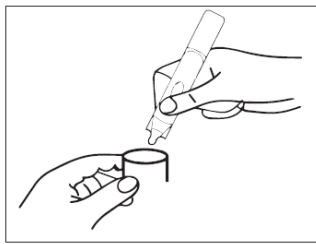
5. Return the remaining single-dose containers to the foil pouch. Return the opened foil pouch to

the box.

6. Hold the top of the single-dose container you have just removed. Twist the body to open it.



7. Put the open end of the single-dose container into the nebuliser bowl and squeeze slowly. Make sure that all the contents are emptied into the nebuliser.



8. Assemble the nebuliser and use it as directed.

After use

- If there is any liquid left over, throw it away, do not save it to use again.
- Throw away any solution remaining in the nebuliser bowl.
- Clean your nebuliser in the recommended way.

If you use more Salbutamol Neutec 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 beats faster than usual
- you feel shaky
- hyperactivity
- acid builds up in your body which may cause your breathing to become faster

These effects usually wear off in a few hours.

If you forget to use Salbutamol Neutec

- If you forget a dose, take the next dose as planned or if your breathing or wheezing gets worse.
- Do not take a double dose to make up for a forgotten dose.

If you stop using Salbutamol Neutec

Do not stop using Salbutamol Neutec without talking to your doctor.

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

4. Possible side effects

If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic reactions (may affect up to 1 in 10 000 people)

If you have an allergic reaction, stop taking Salbutamol Neutec and see a doctor straight away. Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed and collapse.

Talk to your doctor as soon as possible if:

- you feel your heartbeat is uneven or it gives an extra beat. This may affect up to 1 in 10 000 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.**

Lactic acidosis (may affect up to 1 in 10 000 people)

An increase in the amount of lactic acid in the blood (lactic acidosis) is a very rare side effect of salbutamol. This most often affects people who have severe kidney disease.

Symptoms of lactic acidosis include:

- rapid breathing and/or shortness of breath
- feeling cold
- stomach pain, nausea and vomiting

Contact a doctor immediately if you get any of the symptoms listed above. Stop taking Salbutamol Neutec.

Other side effects

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

Common (may affect up to 1 in 10 people)

- feeling shaky
- headache

Uncommon (may affect up to 1 in 100 people)

- faster or stronger heartbeat than usual (palpitations)
- mouth and throat irritation
- muscle cramps

Rare (may affect up to 1 in 1 000 people)

- a low level of potassium in your blood
- increased blood flow to your extremities (peripheral vasodilatation)

Very rare (may affect up to 1 in 10 000 people)

- changes in sleep patterns and changes in behaviour, such as restlessness and excitability

Very rare side effects that may show up in blood tests (may affect up to 1 in 10 000 people)

- lactic acidosis

The following side effects can also happen but the frequency of these are not known:

- chest pain, due to heart problems such as angina pectoris. Tell your nurse doctor, or pharmacist if this occurs. Do not stop using this medicine unless told to do so.

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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

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

Seek urgent medical assistance if the nebulised medicine is not working, even if there is short-term

recovery following use of prescribed nebulised medicine. Your chest problem may be getting worse and you may need a different medicine. Do not take extra Salbutamol Neutec unless your doctor tells you to.

5. How to store Salbutamol Neutec

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the carton, labels and foil pouch after 'EXP'. The expiry date refers to the last day of that month.
- Store below 30 °C.
- Keep single-dose containers in the foil pouch and/or carton in order to protect from light and moisture.
- Do not use this medicine if you notice that the product is discoloured.
- Once a single-dose container is opened, use immediately.
- Any unused solution in the chamber for the nebuliser must be discarded.

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 Neutec contains

- The active substance is salbutamol (as salbutamol sulphate).
- Each 2.5 mL single-dose container contains 2.5 mg of salbutamol (as salbutamol sulphate), which is equivalent to 1 mg of salbutamol per 1 mL.
- The other ingredients are: sodium chloride, sulfuric acid (for pH adjustment) and water for injections.

What Salbutamol Neutec looks like and contents of the pack

A clear, colourless solution contained in disposable translucent low-density polyethylene single-dose containers in strips of 5, overwrapped in a foil pouch.

Salbutamol Neutec is available in packs of 20 single-dose containers.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Sweden	Salbutamol Neutec
Denmark	Salbutamol Neutec
Finland	Salbutamol Neutec
Germany	Salbutamol Neutec 2,5 mg Lösung für einen Vernebler
Iceland	Salbutamol Neutec
Netherlands	Salbutamol Neutec 2,5 mg per 2,5 ml, verneveloplossing
Norway	Salbutamol Neutec
Spain	Salbutamol Neutec 2,5 mg solución para inhalación por nebulizador
France	SALBUTAMOL NEUTEC 2,5 mg/2,5 ml, solution pour inhalation par nébuliseur

Belgium	Salbutamol Neutec 2,5 mg verneveloplossing
Ireland	Salbutamol Neutec 2.5 mg /2.5 ml nebuliser solution
United Kingdom (Northern Ireland)	Salbutamol Neutec 2.5 mg / 2.5 ml

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