



SALAMOL STERI-NEB 5 MG/2.5 ML NEBULISER SOLUTION

salbutamol (as sulphate)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking 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.

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1 WHAT SALAMOL STERI-NEB IS AND WHAT IT IS USED FOR

Your medicine is called Salamol Steri-Neb 5 mg/2.5 ml Nebuliser Solution. It is a beta2-agonist, which helps to manage asthma by dilating (opening up) the airways (or air passages) in the lungs.

Salamol Steri-Neb is used to treat:

- acute severe asthma
- long-term bronchospasm (narrowing of the tubes to the lungs caused by muscle spasm) that does not respond to conventional treatment.

Salamol Steri-Neb is indicated in adults, adolescents and children 4 to 11 years. See section 3.

2 WHAT YOU NEED TO KNOW BEFORE YOU TAKE SALAMOL STERI-NEB

Do NOT take Salamol Steri-Neb:

- if you are allergic to salbutamol sulphate or any of the other ingredients (listed in section 6)
- for the management of premature labour or threatened miscarriage. Some forms of salbutamol can be used for such purposes, however, Salamol Steri-Neb MUST NOT be used.
- if you are taking propranolol or any other non-selective beta blocking drug (see "Other medicines and Salamol Steri-Neb").

Warnings and precautions

Talk to your doctor before taking Salamol Steri-Neb if you:

- have a history of heart disease such as severe heart failure, an irregular or fast heartbeat, or angina (chest pain)
- have diabetes
- suffer from thyroid problems
- have a condition known as glaucoma (raised pressure in your eyes)
- suffer from hypoxia (deficiency of oxygen in the tissues)
- suffer from acute severe asthma. Taking your medicine may lead to low potassium levels in your blood, so your doctor may want you to have regular blood tests to monitor this.

On rare occasions, high doses of Salamol Steri-Neb can cause a very rare but serious condition known as **lactic acidosis** (see section 4). Your doctor may need to regularly check the level of serum lactate in your blood.

Using Salamol Steri-Neb may cause an increase in blood sugar level, which needs to be taken into consideration in patients with **diabetes**.

Use of this medicine may cause difficulty in passing urine in male patients with **enlarged prostate gland**.

Do NOT use Salamol Steri-Neb if you notice the **solution is cloudy**.

Salamol Steri-Neb should be administered in a well-ventilated room, as the nebulised drug is likely to be released into the air.

Do NOT get the solution or mist in your eyes.

Children and adolescents

Salamol Steri-neb is indicated for adolescents and children aged 4 to 11 years. It should not be used in infants under 18 months old. See section 3. Children should be supervised by an adult when using a nebuliser.

Other medicines and Salamol Steri-Neb

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

DO NOT take Salamol Steri-Neb if you are taking the following:

- propranolol or any other non-selective beta blocking drug.

Talk to your doctor if you are taking/using any of the following:

- steroids such as prednisolone
- diuretics (water tablets usually used to treat high blood pressure)
- other sympathomimetic medicines such as metaraminol or xanthine derivatives such as aminophylline or theophylline (used to improve breathing for people with asthma)
- nebulised anticholinergic drugs (such as ipratropium bromide) to treat your asthma
- medicines used to treat high blood pressure such as guanethidine and methyldopa
- antipsychotic and antihypertensive medicines such as reserpine (used to treat high blood pressure or severe agitation)
- tricyclic antidepressants
- some anaesthetics. If you are due to have a surgery, please tell your doctor you are using Salamol.

Pregnancy and breast-feeding

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 any medicine.

Do NOT use Salamol Steri-Neb when pregnant or breast-feeding, unless it is strictly necessary and you have discussed this with your doctor. It is not known if the medicine passes into human breast milk.

Driving and using machines

Salamol Steri-Neb is not expected to affect your ability to drive or operate machinery.

3 HOW TO TAKE SALAMOL STERI-NEB

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

You MUST only use Salamol Steri-Neb in a power-operated nebuliser. The nebuliser turns the solution into a fine mist that you can breathe in through your mouth. Delivery of the aerosol may be by facemask, "T" piece, or breathing tube.

Read the manufacturer's instructions and make sure you know how to use the nebuliser before you take your medicine.

The recommended dose is:

- **Adults (including elderly), adolescents aged 12 years and over and children aged 4 to 11 years**
The starting dose is 2.5 mg taken by wet inhalation. Your doctor may increase this to 5 mg. Treatment may be repeated up to four times a day. For treatment of severe airways obstruction in adults, the maximum of 40 mg per day can be given under medical supervision of a doctor in hospital. Children should be supervised by an adult when they are using a nebuliser.
- **Children under 4 years of age**
Other pharmaceutical forms may be more appropriate for children under 4 years.
- **Infants under 18 months**

Salamol should NOT be used in infants under 18 months of age.

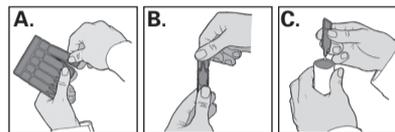
In most patients, a single dose of Salamol Steri-Neb is effective for 4 to 6 hours from administration.

What to do if you think your medicine is not working

You should contact your doctor if the dose seems less effective or is short lasting. Do NOT change the dose you take, or how often you take your medicine without speaking to your doctor first.

How to use your Salamol Steri-Neb Nebuliser

- Prepare your nebuliser for use according to the manufacturer's instructions.
- Remove a Steri-Neb from the labeled strip by twisting and pulling (diagram A).
- Hold the Steri-Neb upright and twist off the cap (diagram B).
- Squeeze the contents into the reservoir of your nebulizer (diagram C).
- Following the manufacturer's instructions, use your nebuliser.
- After you have used your nebuliser, throw away any solution that is left in the reservoir.
- Clean your nebuliser thoroughly.



Do NOT use Salamol Steri-Neb if you notice the **solution is cloudy**.

Do NOT get the solution or mist in your eyes.

Do NOT dilute the solution or mix it with other medicines, unless your doctor tells you to.

Do NOT swallow the solution or use it in injections.

Use this medicine in a well-ventilated room, as the nebulised drug is likely to be released into the air.

If you take more Salamol Steri-Neb than you should

If you (or someone else) swallow(s) or take a lot of the solution all together, or if you think a child has swallowed or taken any of the solution, **contact your nearest hospital casualty department or your doctor immediately**. Take this leaflet, any remaining solution, and the container with you to the hospital, or doctor so that they know which solution has been consumed. An overdose is likely to cause a very rapid heartbeat.

If you forget to take Salamol Steri-Neb

If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. DO NOT take a double dose to make up for a forgotten dose.

If you stop taking Salamol Steri-Neb

Do NOT stop taking your medicine without talking to your doctor first even if you feel better.

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

4 POSSIBLE SIDE EFFECTS

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

If the following happens, STOP taking the solution and tell your doctor or go to the casualty department at your nearest hospital IMMEDIATELY:

- a serious allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives)
- a sudden increase in breathlessness or wheezing, which may be due to paradoxical bronchospasm (narrowing of the air passage or tightening of the chest)
- **lactic acidosis** (rapid breathing, shortness of breath, feeling cold, stomach pain, nausea and vomiting).

Very rarely, some people may experience **chest pain** (due to heart problems such as angina). Tell your doctor as soon as possible, but do NOT stop using this medicine unless told to do so.

The following side effects have also been reported:

Rare (affecting less than 1 in 1,000 patients):

- flushing or redness of the face or skin, increased blood flow to your extremities
- tremors or muscle cramps
- headache
- hyperactivity in young children.

Very rare (affecting less than 1 in 10,000 patients):

- low blood pressure
- collapse
- irregular heartbeat.

Frequency not known:

- low levels of potassium in the blood
- increased heart rate
- decreased blood flow to the parts of the heart, usually caused by narrowing or blocking of blood vessels (myocardial ischaemia).

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.

Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie.

5 HOW TO STORE SALAMOL STERI-NEB

Keep out of the reach and sight of children.

Do not store above 25°C. Do not refrigerate or freeze. Keep container in outer carton to protect from light.

For single use only. Once opened, use immediately. Discard any unused portion. Do not use this medicine after the expiry date, which is stated on the carton and on each Steri-Neb unit after EXP. The expiry date refers to the last day of that month.

Do NOT use Salamol Steri-Neb if you notice the **solution is cloudy**. Never give it to anyone else. It may harm them even if they seem to have the same signs of illness as you have.

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 CONTENTS OF THE PACK AND OTHER INFORMATION

What Salamol Steri-Neb solution contains:

- The active ingredient is salbutamol sulphate.
- The other ingredients are sodium chloride, dilute sulphuric acid, and water for injections.

What Salamol Steri-Neb solution looks like and contents of the pack:

- Each Steri-Neb contains 2.5 ml of a solution that is equivalent to 5 mg of salbutamol (2 mg/ml).

There are 20 Steri-Neb units of your medicine in this pack.

- Strips of 5 Steri-Neb units are packed into foil laminate pouches, which in turn are packed into boxes containing 20 and 100 (ampoules).
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder:

Norton Healthcare Ltd T/A IVAX Pharmaceuticals UK, Ridings Point, Whistler Drive, Castleford, West Yorkshire, WF10 5HX, United Kingdom

Company responsible for manufacture:

IVAX Pharmaceuticals UK, Aston Lane North, Whitehouse Lane Industrial Estate, Preston Brook, Runcorn, Cheshire, United Kingdom, WA7 3FA.

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