



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

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 (referred to as Salamol Steri-Neb throughout this leaflet). It contains a substance called salbutamol, which belongs to a class of medicines called bronchodilators.

Bronchodilators help manage **bronchospasm** (sudden narrowing of the tubes to the lungs caused by muscle spasm), by opening up the air passages in the lungs for up to 4 – 6 hours after administration.

Salamol Steri-Neb is used to treat:

- **asthma**
- **chronic obstructive pulmonary disease (COPD)**, such as chronic bronchitis and emphysema.

If you suffer from asthma, Salamol Steri-Neb can be used to both manage the symptoms before they occur and to relieve symptoms once they occur.

Salamol Steri-Neb is for use in adults, adolescents and children aged 4 to 11 years (see section 3, "How to use Salamol Steri-Neb").

2 What you need to know before you use Salamol Steri-Neb

Do NOT use Salamol Steri-Neb:

- if you are allergic to salbutamol or any of the other ingredients of this medicine (listed in section 6)
- for the general management of premature labour or threatened miscarriage. Although some forms of salbutamol can be used for such purposes, the inhaled salbutamol preparations such as Salamol Steri-Neb MUST NOT be used.

Warnings and precautions

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

- have a history of **heart disease**
- have **heart problems** such as poor blood flow to the heart (coronary insufficiency), severe heart failure, irregular heart rhythm (cardiac arrhythmia), chest pain (angina) or a fast or irregular heart rate
- suffer from **severe and untreated high blood pressure**
- have a bulge in your blood vessel (aneurysm)
- suffer from overactive **thyroid** (hyperthyroidism) or have thyroid problems due to excessive thyroid hormone (thyrotoxicosis)

- have a **low concentration of potassium** in your blood, which is not being treated (hypokalaemia)
- suffer from raised pressure in the eye(s) (**glaucoma**). DO NOT get the solution or mist in your eyes.
- suffer from deficiency of oxygen in the tissues (hypoxia)
- have **diabetes**, especially if it is difficult to control, as salbutamol may cause an increase in your blood sugar level. Using Salamol Steri-Neb with **corticosteroids** can exaggerate this effect (see "Other medicines and Salamol Steri-Neb").
- have a rare, usually noncancerous (benign) tumor that develops in cells in the center of an adrenal gland (pheochromocytoma)
- suffer from **acute severe asthma**. Using this medicine may lead to low potassium levels in your blood, especially if you do not have enough oxygen in your blood (a condition called hypoxia). Your doctor may prescribe you regular blood tests to monitor your potassium levels. For medicines affecting potassium levels, see "Other medicines and Salamol Steri-Neb" in this section of the leaflet.

As severe asthma is a serious and potentially **life-threatening** condition, your doctor will regularly monitor your lung function and how well you are responding to treatment. Your doctor might also decide to prescribe you inhaled and/or oral corticosteroids (anti-inflammatory drugs).

If your intense breathing problems do not improve or get worse following the inhalation, you might need **urgent** medical attention (see section 4, "Possible side effects").

If you are due to have a **surgery**, talk to your doctor or nurse. Salbutamol MUST NOT be used for at least 6 hours before you are given anaesthesia (see "Other medicines and Salamol Steri-Neb").

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

Athletes should be aware the use of salbutamol may cause a positive outcome in **anti-doping control tests**.

On rare occasions, high doses of Salamol Steri-Neb can cause a very rare but serious condition known as **lactic acidosis**, which is caused by an increase in lactate levels in your blood (see section 4, "Possible side effects"). Your doctor may need to regularly check the level of serum lactate in your blood. Symptoms of lactic acidosis include shortness of breath and rapid or deep breathing. If you think you might be suffering from lactic acidosis, **contact your doctor immediately**.

Children and adolescents

Salamol Steri-Neb is indicated for adolescents and children aged 4 to 11 years. Children should be supervised by an adult when using a nebuliser.

Children and their caregivers should be encouraged and trained to use a mouthpiece instead of a facemask as soon as possible.

Other medicines and Salamol Steri-Neb

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.

DO NOT use Salamol Steri-Neb if you are taking:

- propranolol or any other non-selective beta-blocking medicine (used to treat heart problems and high blood pressure).

Talk to your doctor if you are taking any of the following medicines.

The effects of salbutamol may be altered when used with:

- guanethidine and methyl dopa (medicines used to treat high blood pressure)
- reserpine (used to treat psychosis or high blood pressure)
- tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs), such as moclobemide (used to treat depression)
- large doses of other sympathomimetic drugs, such as ephedrine (used to treat low blood pressure and breathing problems).

Low potassium levels (hypokalaemia) may be worsened when salbutamol is used in particular with:

- xantine derivatives, such as aminophylline or theophylline (used to improve breathing for people with asthma)

- glucocorticoids and other steroids (used to treat mainly inflammation and immune system disorders)
- diuretics, also known as "water tablets" (used to treat high blood pressure)
- cardiac glycosides (used to treat severe heart failure and certain irregular heartbeats).

Using Salamol Steri-Neb with **corticosteroids** can exaggerate the increase in blood sugar. This should be taken into consideration in patients with **diabetes** (see "Warnings and precautions").

In some cases, combined use of salbutamol and ipratropium, which is also used for treatment of COPD and asthma, has been reported to cause raised pressure in the eye(s) (**acute angle glaucoma**). Talk to your doctor before using these medicines together. If you are to use salbutamol and ipratropium together, avoid any contact of the medicines with your eyes.

Some **anaesthetics** (such as chloroform, cyclopropane or halothane) and salbutamol MUST be used **at least 6 hours apart**. Talk to your doctor or nurse if you are due to have a **surgery** (see "Warnings and precautions").

Talk to your doctor, pharmacist or nurse before taking any other medicine.

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 any medicine.

During pregnancy, the use of Salamol Steri-Neb is NOT recommended, unless the expected benefit to the mother is greater than any possible risk to the baby.

When breast-feeding, the use of Salamol Steri-Neb is NOT recommended unless the expected benefit to the mother is greater than any possible risk to the baby. The medicine may pass into breast milk and affect the baby.

There is no evidence of salbutamol affecting human fertility.

Driving and using machines

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

3 How to use Salamol Steri-Neb

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

The recommended dose is:

Adults (including elderly) and adolescents aged 12 years and over

- The starting dose is 5 mg taken by wet inhalation. Your doctor may increase this to 5 mg. Treatment may be repeated up to four times a day.
- The maximum daily dose is normally 20 mg per day.
- For treatment of severe airways obstruction, the maximum dose of 40 mg per day can only be given under strict medical supervision in hospital.

Children aged 4 to 11 years

- The starting dose is 2.5 mg taken by wet inhalation. Their doctor may increase this to 5 mg. Treatment may be repeated up to four times a day.
- Children should be supervised by a responsible 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.

Method of administration

Salamol Steri-Neb MUST be used by inhalation only and breathed in through the mouth.

The solution MUST NOT be injected or swallowed.

DO NOT get the solution or mist in your eyes.

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

You can use Salamol Steri-Neb by breathing

it in through a facemask, "T" piece, or breathing tube.

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

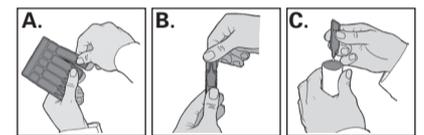
Normally, Salamol Steri-Neb solution is used undiluted. However, if prolonged delivery time of over 10 minutes is desired, your doctor or nurse will dilute Salamol Steri-Neb using sterile normal saline. DO NOT dilute the solution or mix it with other medicines yourself, unless your doctor has instructed you to do so.

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

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

Instructions for use

- 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 nebuliser (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.



Talk to your doctor if you are not sure how to use Salamol Steri-Neb or the nebuliser.

If your medicine is not working properly

Talk to your doctor if you think your current dose has become less effective or is short-lasting. DO NOT change the dose you use, or how often you use your medicine without speaking to your doctor first.

If your intense breathing problems do not improve or get worse following the inhalation, you might need medical attention (see section 4, "Possible side effects").

If you use more Salamol Steri-Neb than you should

If you (or someone else) swallow(s) or uses a lot of the solution, or if you think a child has swallowed or used any of the solution without supervision, **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 what substance has been consumed or used. An overdose may cause side effects described in section 4 of this leaflet.

If you forget to use Salamol Steri-Neb

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

If you stop using Salamol Steri-Neb

DO NOT stop using 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, pharmacist or nurse.

4 Possible side effects

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

STOP using the solution and tell your doctor or go to the casualty department at your nearest hospital IMMEDIATELY if:

- your breathing problems worsen or you experience wheezing following a dose of Salamol Steri-Neb
- you have signs of a **serious allergic reaction** (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives; low blood pressure leading to collapse)
- **lactic acidosis** (rapid breathing, shortness of breath, feeling cold, stomach pain, nausea and vomiting).

These are very serious but rare side effects.

You may need **urgent** medical attention or hospitalisation.

If you suffer from heart disease, **tell your doctor or go to the casualty department at your nearest hospital IMMEDIATELY** if you experience chest pain or any symptoms of your heart disease worsening.

Talk to your doctor, pharmacist or nurse if you experience any of the following side effects:

Common (affecting less than 1 in 10 patients):

- tremor
- headache
- heart rate that exceeds normal resting rate (tachycardia).

Uncommon (affecting less than 1 in 100 patients):

- palpitations
- mouth and throat irritation
- muscle cramps.

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

- low levels of potassium in the blood (hypokalaemia)
- flushing or redness of the face or skin, increased blood flow to your extremities (peripheral vasodilatation).

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

- rapid and irregular heart beat (atrial fibrillation)
- rapid heart rhythm due to improper electrical activity of the heart (supraventricular tachycardia)
- premature electrical impulse in the heart, generated above the level of the heart chamber called ventricle (supraventricular extrasystoles)
- hyperactivity. In addition, children up to 12 years of age may experience the state of overexcitement, sleeping problems, and hallucinations.

Frequency not known:

- 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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

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**.

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 Nebuliser

Solution contains:

- The active ingredient is salbutamol sulphate. Each Steri-Neb ampoule contains 2.5 ml of a solution that is equivalent to 5 mg of salbutamol (2 mg/ml).
- The other ingredients are sodium chloride, dilute sulphuric acid (for pH adjustment), and water for injections.

What Salamol Steri-Neb Nebuliser

Solution looks like and contents of the pack:

A unit dose, blow molded, hermetically sealed, low-density polyethylene Steri-Neb ampoule, containing 2.5 ml of solution. Clear,

colourless to pale yellow, aqueous solution.

Steri-Neb are packed into foil laminate pouches, containing strips of 5 Steri-Neb per pouch.

Available in cartons of 20 and 100 Steri-Neb. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Teva B.V.,
Swensweg 5,
2031GA Haarlem,
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Manufacturer:

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