

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Salamol Steri-Neb 2.5 mg/2.5 ml Nebuliser Solution** salbutamol (as sulfate)

**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, nurse or pharmacist.
- This medicine has been prescribed for you. 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 2.5 mg/2.5 ml Nebuliser Solution (referred to as Salamol Steri-Neb throughout this leaflet). Salamol Steri-Neb contains a medicine called salbutamol, which belongs to a group of medicines called 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.

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.

A Nebule is 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.

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 sulfate 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, nurse or pharmacist** before taking Salamol Steri-Neb if:

- you have a history of **heart disease**
- you 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
- you suffer from **severe and untreated high blood pressure**
- you have a bulge in your blood vessel (aneurysm)
- you suffer from overactive **thyroid** (hyperthyroidism) or have thyroid problems due to excessive thyroid hormone (thyrotoxicosis)
- you have a **low concentration of potassium** in your blood, which is not being treated (hypokalaemia)
- you suffer from raised pressure in the eye(s) (**glaucoma**). DO NOT get the solution or mist in your eyes.
- you suffer from deficiency of oxygen in the tissues (hypoxia)
- you 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”).
- you have a rare, usually noncancerous (benign) tumor that develops in cells in the center of an adrenal gland (pheochromocytoma)
- you 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**.

If you are using Salamol Steri-Neb 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.

### **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**

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go to hospital.

In particular tell your doctor, nurse or pharmacist if you are taking:

- medicines for an irregular or fast heartbeat e.g. propranolol
- other medicines for your asthma
- medicines used to treat high blood pressure e.g. guanethidine and methyldopa
- reserpine (used to treat high blood pressure or severe agitation)
- 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”).

### **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 or pharmacist for advice before taking this 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, nurse or pharmacist if you are not sure.

#### **The recommended dose is:**

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

- 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.
- 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.

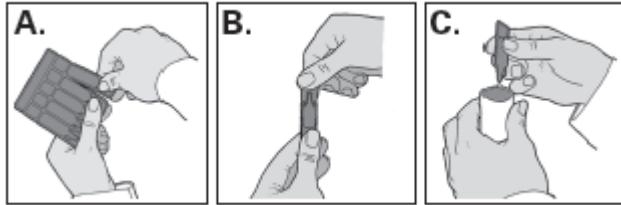
In most patients, a single dose of Salamol Steri-Neb is effective for 4 to 6 hours from administration.

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 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 Salamol Steri-Neb**

- If you forget a dose, take it as soon as you remember it.
- However, if it is time for the next dose, skip the missed 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 Salamol Steri-Neb without talking to your doctor.

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

## **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 Salamol Steri-Neb 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.

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 as soon as possible if:**

- you feel your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while
- you may feel your heartbeat is uneven or it gives an extra beat
- these affect less than 1 in 10 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 Salamol Steri-Neb. This most often affects people who have severe kidney disease.

Symptoms of lactic acidosis include:

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

**Contact a doctor immediately if you get these symptoms. Stop taking Salamol Steri-Neb**

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

**Uncommon** (may affect up to 1 in 100 people):

- palpitations
- mouth and throat irritation
- muscle cramps.

**Rare** (may affect up to 1 in 1,000 people):

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

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

- 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)
- changes in sleep patterns and changes in behaviour, such as restlessness and excitability.
- hyperactivity. In addition, children up to 12 years of age may experience the state of overexcitement, sleeping problems, and hallucinations.

**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:**

- decreased blood flow to the parts of the heart, usually caused by narrowing or blocking of blood vessels (myocardial ischaemia).

- chest pain, due to heart problems such as angina. Tell your doctor, nurse 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 HPRA Pharmacovigilance. Website: [www.hpra.ie](http://www.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 sight and reach 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 sulfate. Each Steri-Neb ampoule contains 2.5 ml of a solution that is equivalent to 2.5 mg of salbutamol (1 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  
The Netherlands

#### **Manufacturer:**

Merckle GmbH, Ludwig-Merckle-Strasse 3,

D-89143 Blaubeuren,  
Germany.

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