

Package Leaflet: Information for the user

Saline Steri-Neb 0.9% w/v Nebuliser Solution Sodium Chloride 2.5mL

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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

Saline Steri-Neb is used to dilute nebuliser solutions. The nebuliser turns the solution into a fine mist which you can breathe in. You should carefully read the leaflet supplied with the nebuliser solutions before using them with Saline Steri-Neb.

2 WHAT YOU NEED TO KNOW BEFORE YOU USE SALINE STERI-NEB

Do NOT use Saline Steri-Neb if you:

- are allergic (hypersensitive) to sodium chloride or any of the other ingredients of this medicine.

Taking other medicines

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

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or breast-feeding, ask your doctor for advice before taking any medicine.

Driving and using machines

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

3 HOW TO USE SALINE STERI-NEB

Always use Saline Steri-Neb exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You must only use Saline Steri-Neb in a nebuliser. Do not swallow the solution or use it in injections. Read the manufacturer's instructions and make sure you know how to use the nebuliser before you take your medicine.

- Prepare your nebuliser for use according to the manufacturer's instructions

- Empty the solution that needs diluting into the nebuliser following the manufacturer's instructions
- Remove a Steri-Neb from the labelled 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.

Adults, children and the elderly

Follow your doctor's instructions when you are diluting nebuliser solutions.

Mix up a fresh batch of the solution before each dose and use as directed by your doctor.

If you use more Saline Steri-Neb than you should

If you (or someone else) swallow any of the solution, or if you think a child has swallowed any of the solution, contact your nearest hospital casualty department or your doctor immediately. Please 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.

If you forget to use Saline Steri-Neb

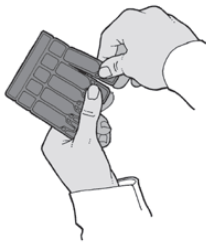
If you forget to use the nebuliser, use it as soon as you remember, unless it is nearly time to use it again. Do not take a double dose of your medicine to make up for a forgotten dose.

If you stop using Saline Steri-Neb

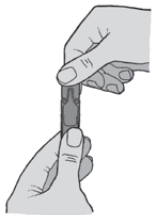
Do not stop taking your medicine without talking to your doctor first even if you feel better.

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

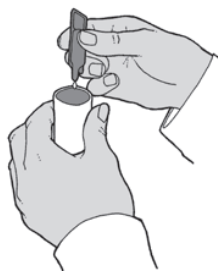
A.



B.



C.



4 POSSIBLE SIDE EFFECTS

Like all medicines, the medicine you breathe in with Saline Steri-Neb could cause some side effects, although not everybody gets them. The leaflet that comes with that medicine will give you more information on this.

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. By reporting side effects you can help provide more information on the safety of this medicine.

5 HOW TO STORE SALINE STERI-NEB

- **Keep out of the sight and reach of children.**
- Do not store above 25°C. Do not refrigerate or freeze.
- For single use only. Discard any unused portion.
- Do not use Saline Steri-Neb after the expiry date which is stated on the carton, on the laminate foil and on each Steri-Neb unit after EXP. The expiry date refers to the last day of the month.
- Do not use Saline 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 Saline Steri-Neb contains:

Each Saline Steri-Neb contains 2.5ml of a 0.9% w/v solution of sodium chloride. The other ingredient is water for injections.

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

- A unit dose blow moulded hermetically sealed 3 ml ampoule containing 2.5 ml of a clear, colourless aqueous solution.
 - Strips of 5 Steri-Neb are packed into foil laminate pouches, which in turn are packed into boxes containing 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

Company responsible for manufacture:

IVAX Pharmaceuticals UK,
Aston Lane North,
Whitehouse Vale Industrial Estate,
Preston Brook, Runcorn,
Cheshire, WA7 3FA,
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Merckle GmbH, Ludwig-Merckle-Strasse 3,

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‘Steri-Neb’ is a trademark