Package leaflet: Information for the user

Saline Steripoules 2.5ml

(Sodium Chloride 0.9% w/v)

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 Saline Steripoules 2.5ml are and what they are used for
- 2. What you need to know before you use Saline Steripoules 2.5ml
- 3. How to use Saline Steripoules 2.5ml
- 4. Possible side effects
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- 6. Contents of the pack and other information

1. What Saline Steripoules 2.5ml are and what they are used for

Saline Steripoules 2.5ml contain a solution (physiological saline) which is used to dilute other nebuliser solutions.

2. What you need to know before you use Saline Steripoules 2.5ml

Do not inject or orally administer Saline Steripoules 2.5ml.

Do not use Saline Steripoules 2.5ml:

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

Other medicines and Saline Steripoules 2.5ml

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Saline Steripoules 2.5ml with food and drink

Food and drink have no known influence.

Pregnancy, breast-feeding and fertility

As with all medicines, particular caution must be exercised during the first trimester of pregnancy. 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 and they will decide what to do. It may still be safe for you to use this solution.

Driving and using machines

This solution has no known influence on your ability to drive and use machines.

3. How to use Saline Steripoules 2.5ml

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

First use of Saline Steripoules

The first time you use this solution should be under close medical supervision.

Saline Steripoules 2.5ml are used to dilute other nebuliser solutions. They must only be administered by inhalation from a suitable nebuliser. (This product should not be swallowed). A nebuliser is a machine which turns the nebuliser solution into a fine spray which you can then inhale, usually through a mask.

Preparing the nebuliser and nebuliser solutions:

- 1. Make sure that you are fully familiar with the operation of your nebuliser. Your doctor will instruct you in how to correctly use the nebuliser and nebuliser solutions. You should also carefully read the instructions provided with the nebuliser.
- 2. Prepare the nebuliser for use.
- 3. Separate a Steripoule from the strip by carefully pulling and twisting (Figure 1). **Never** use one that is already open.
- 4. Hold the Steripoule upright and twist off the tab (Figure 2). Use the contents of the Steripoule immediately after opening.
- 5. Use the contents of the Steripoule to dilute the other nebuliser solution as instructed by the doctor. Squeeze the prescribed amount of sodium chloride solution from the Steripoule into the nebuliser reservoir (Figure 3).
- 6. Assemble the nebuliser and use it as instructed by your doctor. Care should be taken to ensure that the nebuliser mist (or the solution) does not enter your eyes.
- 7. After nebulisation throw away any solution remaining in the nebuliser and clean the nebuliser as instructed.



Fig.1 Separation

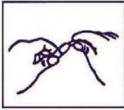


Fig.2 Opening

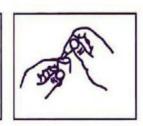


Fig.3 Squeezing into nebuliser reservoir

If your treatment is less effective than usual

If your treatment is less effective than usual or the effect does not last as long as usual, do not attempt to exceed your prescribed dose. You should contact your doctor immediately to discuss the situation.

If you use more Saline Steripoules 2.5ml than you should

If you have taken a much larger dose than recommended, you should contact your nearest casualty department or tell your doctor immediately. Take this leaflet and any remaining medicine with you.

If you forget to use Saline Steripoules 2.5ml

If you miss a dose, take it as soon as you remember and then continue as before. Do not take a double dose to make up for a forgotten dose.

If you stop using Saline Steripoules 2.5ml

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

4. Possible side effects

This solution is not expected to cause any undesirable effects in normal use.

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 Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Saline Steripoules 2.5ml

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, foil bag or plastic ampoules. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the Steripoules in the foil bag within the outer carton in order to protect the product from light and moisture.

Do not use this medicine if you notice that the packaging or any of the plastic ampoules are damaged, or if the solution in the plastic ampoules is no longer clear and colourless.

Do not keep or use a Steripoule which has been opened previously – throw it away.

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 Saline Steripoules 2.5ml contains

The active substance is sodium chloride. Each Steripoule contains 2.5ml of 0.9% w/v solution of sodium chloride.

The other excipient is water for injections.

What Saline Steripoules look like and the contents of the pack

Each carton of Saline Steripoules 2.5ml contains 20 plastic ampoules (Steripoules) packed in strips of 10 ampoules. Each strip is individually wrapped in a foil bag. Each Steripoule contains 2.5ml of a clear, colourless solution for use only through a nebuliser.

Marketing Authorisation Holder

Galen Limited Seagoe Industrial Estate Craigavon BT63 5UA UK

Manufacturer

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