

PACKAGE LEAFLET: INFORMATION FOR THE USER

0.9% SODIUM CHLORIDE INTRAVENOUS INFUSION SOLUTION Sodium chloride

Read all of this leaflet carefully before being given 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 nurse
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet

1. What 0.9% Sodium Chloride Intravenous Infusion Solution is and what it is used for
2. What you need to know before you are given 0.9% Sodium Chloride Intravenous Infusion Solution
3. How 0.9% Sodium Chloride Intravenous Infusion Solution is given
4. Possible side effects
5. How to store 0.9% Sodium Chloride Intravenous Infusion Solution
6. Contents of the pack and other information

1. WHAT 0.9% SODIUM CHLORIDE INTRAVENOUS INFUSION SOLUTION IS AND WHAT IT IS USED FOR

0.9% Sodium Chloride Intravenous Infusion Solution is a clear colourless to faintly strawcoloured solution of sodium chloride in water. The solution is stored in a sealed flexible plastic bag.

Sodium chloride (salt) helps to maintain the correct balance of fluid in and around the body's cells and tissues. Sodium chloride infusions are given to add water to tissues which are dehydrated and to help to restore the normal salt balance.

Sodium chloride infusions may be given alone but may be given with other medicines added. You will be given sodium chloride infusions in hospital by a doctor or nurse.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN 0.9% SODIUM CHLORIDE INTRAVENOUS INFUSION SOLUTION

You MUST NOT be given sodium chloride infusions if you:

- have an allergy to sodium chloride or any of the other ingredients.

Warnings and precautions

Talk to your doctor or nurse if you:

- have heart failure, cardio-pulmonary disease, kidney problems, high blood pressure, liver disease, or oedema (swelling)
- have high serum levels of sodium ("hypernatraemia")

- have pre-eclampsia of pregnancy
- are receiving drugs which may increase sodium retention are very young or elderly.

Other medicines and 0.9% Sodium Chloride Intravenous Infusion Solution

Tell your doctor if you are taking or have recently taken any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, or think you may be pregnant or are planning to have a baby, ask your doctor for advice before being given this medicine.

Driving and using machines

Sodium chloride infusion has no effect on your ability to drive or use machines.

3. HOW 0.9% SODIUM CHLORIDE INTRAVENOUS INFUSION SOLUTION IS GIVEN

Sodium chloride infusion will be given to you in hospital.

You will receive the solution by infusion into a vein (usually in the arm), administered by a doctor or nurse. The amount and rate at which the infusion is given depends on your requirements. Your doctor will decide on the correct volume for you to receive.

Your doctor will check your response to the treatment by the relief of your symptoms, and will probably take samples of blood and urine for laboratory testing.

If you are given more sodium chloride infusion than you should

It is unlikely you will be given too much solution as your doctor or nurse will be checking your response to the treatment. Infusion of too much sodium chloride solution can lead to the build up of sodium in the blood, which can lead to dehydration of some organs of the body and to loss of potassium. If you are concerned about the volume of solution given, or are worried about any effects you notice, talk to your doctor or nurse.

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

4. POSSIBLE SIDE EFFECTS

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

The infusion should be stopped immediately if you experience an adverse reaction.

If you are given the solution for a long time, you may notice the following:

- irritation, swelling, redness and tenderness at the site of injection.

The balance of some chemicals in your blood may become upset. You may notice the following:

- swelling, especially of the legs.

- feel tired, weak, dizzy, have a headache or problems with vision
- or a fast or irregular heart beat
- feel sick (nausea) and have an upset stomach, loss of appetite
- drowsiness, lack of energy
- cramp or discomfort of the muscles, confusion or disorientation
- thirst, dry mouth, dark urine

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

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 0.9% SODIUM CHLORIDE INTRAVENOUS INFUSION SOLUTION

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Do not freeze. Store in the original outer container. Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

The solution should only be used if it is clear and the container is not damaged. It should be used immediately on removal from the overwrap. For single use only. Any unused solution in the bag must be discarded.

Do not throw away any medicines via wastewater or household waste. The doctor or nurse will dispose of this medicine. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What 0.9% Sodium Chloride Intravenous Infusion Solution contains

The **active** substance is sodium chloride. Each litre of solution contains 9g sodium chloride. Each litre contains 154 mmol sodium and 154 mmol chloride. The **other** ingredient is water for injections.

What 0.9% Sodium Chloride Intravenous Infusion Solution looks like and contents of the pack

Sodium chloride infusion is a clear, colourless to faintly straw-coloured solution. The solution for infusion is packaged in a plastic bag or flexible container with an integral infusion set for direct connection to a catheter. It is available in sizes of 50ml, 100ml, 250ml, 500ml and, depending on the container type, 1000ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

CARELIDE

Rue Michel Raillard
59420 MOUVAUX
FRANCE

Manufacturer

CARELIDE

Rue Michel Raillard
59420 MOUVAUX
France

PA22859/001/001