

Package Leaflet: Information for the user
Sodium Chloride 30% w/v Concentrate for Solution for Infusion
Sodium chloride

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.**
- **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 Sodium Chloride 30% w/v Concentrate for Solution for Infusion is and what it is used for**
2. **What you need to know before you use Sodium Chloride 30% w/v Concentrate for Solution for Infusion**
3. **How to use Sodium Chloride 30% w/v Concentrate for Solution for Infusion**
4. **Possible Side Effects**
5. **How to store Sodium Chloride 30% w/v Concentrate for Solution for Infusion**
6. **Contents of the pack and other information**

1. What Sodium Chloride 30% w/v Concentrate for Solution for Infusion is and what it is used for

This medicine is a concentrated electrolyte solution for infusion into a large vein. When diluted and mixed thoroughly with another fluid it is used for rehydration.

2. What you need to know before you use Sodium Chloride 30% w/v Concentrate for Solution for Infusion

You will be given this medicine in hospital by a doctor or nurse.

Do not use this medicine if you:

- Have suffered with heart disease
- Have suffered with high blood pressure
- Have suffered with diabetes mellitus

Check with your doctor if you are concerned about any of the above.

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before using Sodium Chloride 30% w/v Concentrate for Solution for Infusion if:

- You are suffering from congestive heart failure
- You have problems with your kidneys
- You have suffered from pulmonary oedema (fluid on the lungs)
- You have suffered from pre-eclampsia (high blood pressure associated with pregnancy)
- You have suffered from peripheral oedema (swelling of hands and feet)
- If you have high blood pressure, swelling and protein in the urine during the last 3 months of pregnancy (toxaemia of pregnancy)
- This medicine is being used in a child
- This medicine is being used in an elderly person

This medicine should be given with care if any of the above applies to you.

Check with your doctor if you are concerned about any of the above.

Other Medicines and Sodium Chloride 30% w/v Concentrate for Solution for Infusion

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important if you are taking:

- **Streptomycin**

3. How to use Sodium Chloride 30% w/v Concentrate for Solution for Infusion

The doctor will decide what dose of this medicine you should be given. Check with your doctor if you are not sure.

This medicine is a concentrated solution and must be diluted before use. It is given by infusion into a large vein at a rate not exceeding 100 mL/hr. Doses will be adjusted by the doctor, but the usual Sodium Chloride requirements for an adult can be satisfied by infusion of the equivalent of 1 litre of Sodium Chloride 0.9% w/v daily.

If a dose of this medicine is not given at the correct time – the dose should be given as soon as remembered. The next dose should be given at the usual time. A double dose should not be given.

If more of this medicine is given than should be – tell your doctor as soon as possible. If you are a medical practitioner administering this medicine please refer to the Summary of Characteristics.



Additional information for Healthcare Professionals
(as stated on the Summary of Product Characteristics)

Therapeutic Indications

The product is used for rehydration only when diluted. Before administration, the concentrate must be diluted and thoroughly mixed with a larger volume of fluid.

Posology and Method of Administration

When concentrations of 3 and 5% w/v are indicated, the solution should be administered into a large vein, at a rate not exceeding 100 mL per hour.

Adults, Children and the elderly

Concentration and sodium chloride dosage for intravenous use are determined by several factors, including age, weight and clinical condition of the patient. The usual sodium and chloride requirements for adults can be satisfied by infusion of the equivalent of 1 litre of sodium chloride 0.9% w/v daily.

Sodium Chloride 30% w/v Concentrate for Solution for Infusion should be diluted sufficiently to obtain an isotonic (0.9% w/v) solution. An isotonic solution can be prepared by diluting 30 mL Sodium Chloride 30% w/v Concentrate for Solution for Infusion to 1 litre with a non-electrolyte solution or water for injections.

Continued overleaf

4. Possible side effects

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

Serious side effects are:

- Kidney failure
- Convulsions
- Respiratory arrest
- Coma

Tell your doctor, pharmacist or nurse immediately if you think you have symptoms related to the above.

Other side effects

The most common side effects are:

- Nausea or vomiting
- Diarrhoea
- Stomach cramps
- Dry mouth or stuffy nose
- Sweating and high temperature (fever)
- Low blood pressure when standing. This may make you feel dizzy or faint
- Fluid on the lungs
- Headache
- Rapid heartbeat
- Feeling weak
- Restlessness or irritability

Very rare side effects are:

- Muscular twitching

Tell your doctor, pharmacist or nurse immediately if you think you have any of the above symptoms or other problems.

Reporting Side Effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 Sodium Chloride 30% w/v Concentrate for Solution for Infusion

- Keep this medicine out of the sight and reach of children.
- This medicine has an expiry date printed on the ampoule, vial and carton. Do not use this medicine after the expiry date. The expiry date refers to the last day of the month. Before use the doctor or nurse will check that the medicine has not passed this date and the medicine does not show signs of deterioration.
- Store this medicine below 25°C.
- Do not throw away any medicines via waste water. These measures will help to protect the environment.

6. Contents of the pack and other information

What Sodium Chloride 30% w/v Concentrate for Solution for Infusion contains

- The active substance is sodium chloride at a strength of 300mg per mL (5.13 mmol sodium and chloride per mL).
- The other ingredient is Water for Injections.

What Sodium Chloride 30% w/v Concentrate for Solution for Infusion looks like and contents of pack:

This medicine is a clear and colourless solution. This medicine is available in a 10 mL ampoule containing 3 g of Sodium Chloride; a 50 mL vial containing 15 g Sodium Chloride and a 100 mL vial containing 30 g Sodium Chloride. The medicine is packed into cartons containing 10 ampoules, 1 vial or 10 vials. Both pack sizes of vials may not be available at the same time.

Marketing Authorisation Holder and Manufacturer:

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Continued from overleaf

Sodium Chloride 0.9% w/v injections are often used as diluents for the infusion of drug additives, and 0.9% w/v solutions of sodium chloride are widely used for sterile irrigation and dilution purposes.

Incompatibilities

Streptomycin sulfate is stated to be incompatible with sodium chloride. The addition of sodium chloride to mannitol 20 - 25% may cause precipitation of the mannitol.

As with all parenteral concentrate solutions, incompatibility of diluting fluids with the concentrate should be assessed before addition. In the absence of compatibility studies, this concentrate must not be mixed with other medicinal products.