

PACKAGE LEAFLET: INFORMATION FOR THE USER

SODIUM CHLORIDE 0.18%w/v GLUCOSE 4%w/v SOLUTION FOR INFUSION Sodium chloride and glucose anhydrous

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 Sodium Chloride 0.18%w/v Glucose 4%w/v Solution for Infusion is and what it is used for
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1. WHAT SODIUM CHLORIDE 0.18%w/v GLUCOSE 4%w/v SOLUTION FOR INFUSION IS AND WHAT IT IS USED FOR

Sodium Chloride 0.18%w/v Glucose 4%w/v Solution for Infusion is a clear, colourless to faintly straw-coloured solution of sodium chloride and glucose in water. The solution is stored in a sealed flexible plastic bag.

Glucose sodium chloride solution is given to replace fluid loss from the body. Glucose is a simple sugar, which provides a source of energy. Sodium chloride (salt) helps to maintain the correct balance of fluid in and around the body's cells and tissues.

Glucose sodium chloride solution may be given alone but may be given with other medicines added.

You will be given glucose sodium chloride solution in hospital by a doctor or nurse.

The solution should be used in children only in specialist paediatric units under expert medical supervision, to maintain the correct balance of fluids and salts.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN SODIUM CHLORIDE 0.18%w/v GLUCOSE 4%w/v SOLUTION FOR INFUSION

You MUST NOT be given this solution if you have:

- an allergy to sodium chloride, glucose or any of the other ingredients

- if you are having regular treatment for abnormal fluid levels
- after ischaemic stroke
- within 24 hours of head injury, or
- if you have abnormal levels of hydration with low sodium salt levels.

Warnings and precautions

Talk to your doctor or nurse if you:

- have **heart failure, kidney problems, high blood pressure, liver disease, or oedema** (swelling)
- have **diabetes mellitus**
- have **pre-eclampsia** of pregnancy
- are receiving **salt steroids**
- are **elderly**.

Use in children

The solution should be used in children only in specialist paediatric units under expert medical supervision, to maintain the correct balance of fluids and salts.

Other medicines and Sodium Chloride 0.18%w/v Glucose 4%w/v Solution for Infusion

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.

The solution should be used with care during pregnancy and breast-feeding to avoid extreme levels of glucose in the mother and the foetus or baby.

Driving and using machines

Glucose sodium chloride solution has no effect on your ability to drive or use machines.

3. HOW SODIUM CHLORIDE 0.18%w/v GLUCOSE 4%w/v SOLUTION FOR INFUSION IS GIVEN

Glucose sodium chloride solution will be given to you in hospital.

The solution should be used in children only in specialist paediatric units under expert medical supervision, to maintain the correct balance of fluids and salts.

You will receive the solution by infusion into a vein (usually in your arm), administered by a doctor or nurse. The amount and rate at which the infusion is given depends on your requirements. Normally the volume given to adults is between 0.5 and 3 litres per day. 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.

Blood and urine samples, and urine flow, should be closely monitored when treating children.

If you are given more glucose sodium chloride solution 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 glucose sodium chloride solution can lead to high blood sugar levels or the build up of sodium in the blood, which can lead to dehydration of some organs of the body, and oedema (swelling) and to loss of potassium. In children low levels of sodium salts needs urgent specialised medical attention.

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. Low sodium levels may occur and need immediate medical action.

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 weak, drowsy or dizzy, have a headache or a fast heart beat.
- feel sick (nausea) and have an upset stomach.

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 SODIUM CHLORIDE 0.18%w/v GLUCOSE 4%w/v SOLUTION FOR INFUSION

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

Do not store above 25°C. Do not freeze. Store in the original package to prevent moisture loss. 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 Sodium Chloride 0.18%w/v Glucose 4%w/v Solution for Infusion contains The **active** substances are sodium chloride and glucose anhydrous (glucose) as glucose monohydrate. Each litre of solution contains 1.8g sodium chloride (0.18%w/v) and 40g glucose (4%w/v). Each litre contains 30mmol sodium, 30mmol chloride and 222mmol glucose. The **other** ingredient is water for injections.

What Sodium Chloride 0.18%w/v Glucose 4%w/v Solution for Infusion looks like and contents of the pack

Sodium Chloride 0.18% w/v Glucose 4% w/v Solution for Infusion is a clear, colourless to faintly straw-coloured solution. The solution for infusion is packaged in a plastic bag. It is available in sizes of 500ml and 1000ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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