

PACKAGE LEAFLET: INFORMATION FOR THE USER

5% GLUCOSE INTRAVENOUS INFUSION SOLUTION 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 5% Glucose Intravenous Infusion Solution is and what it is used for
2. What you need to know before you are given 5% Glucose Intravenous Infusion Solution
3. How 5% Glucose Intravenous Infusion Solution is given
4. Possible side effects
5. How to store 5% Glucose Intravenous Infusion Solution
6. Contents of the pack and other information

1. WHAT 5% GLUCOSE INTRAVENOUS INFUSION SOLUTION IS AND WHAT IT IS USED FOR

5% Glucose Intravenous Infusion Solution is a clear colourless to faintly straw-coloured solution of glucose in water. The solution is stored in a sealed flexible plastic bag.

Glucose is a simple sugar, which provides a source of energy. Glucose infusions are used to replace fluid loss from the body, to restore the body's water balance.

Glucose infusions can be given alone but may be given with added salts such as sodium or potassium. You may be given glucose solution with other medicines added, depending on your condition.

Glucose infusions will be given to you in hospital by a doctor or nurse.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN 5% GLUCOSE INTRAVENOUS INFUSION SOLUTION

You must NOT be given this solution if you have:

- an **allergy** to glucose or any of the other ingredients
- **hyperglycaemia** (high levels of glucose in the blood)
- a condition of **water excess**, such as liver disease or heart failure.

Warnings and precautions

Talk to your doctor or nurse if you:

- have **diabetes mellitus**
- have **kidney failure**
- have suffered a **stroke**
- are **pregnant** or are **breast-feeding**

Other medicines and 5% Glucose 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.

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

3. HOW 5% GLUCOSE INTRAVENOUS INFUSION SOLUTION IS GIVEN

Glucose infusion will be given to you in hospital.

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 2 and 10 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.

If you are given more glucose 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. If you receive too much solution, the balance of some chemicals in your blood may be upset and levels of glucose in your blood or urine may be raised. You may feel weak, confused, and have a fast heart rate. If you are concerned about the volume of solution given, or are worried about any affects 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.

Glucose infusion can cause upset fluid and salt (electrolyte) levels which may cause patients to feel weak, drowsy, confused or nauseous, or have muscle cramps. Heart rhythm may be abnormal and heart rate may be fast. Glucose infusions can cause low levels of blood glucose which may result in headaches, sweating, shaking, numbness, slurred speech or confusion.

Glucose infusions can cause irritation and discomfort at the site of infusion.

Some diabetic patients receiving glucose solution with insulin may feel weak, drowsy or dizzy because of upset salt levels.

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 5% GLUCOSE 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 5% Glucose Intravenous Infusion Solution contains

The **active** substance is glucose anhydrous (glucose) as glucose monohydrate.

Each litre of solution contains 50g glucose as glucose monohydrate.

Each litre contains 278 mmol glucose.

The **other** ingredient is water for injections.

What 5% Glucose Intravenous Infusion Solution looks like and contents of the pack Glucose 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 50ml, 100ml, 250ml and 500ml and, depending on the container type, 1000ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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1, rue Alexander Fleming

69007 Lyon

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Manufacturer

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