PACKAGE LEAFLET: INFORMATION FOR THE USER

5 % w/v Glucose Intravenous Infusion BP Solution for Infusion
Glucose

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.

What is in this leaflet

1. What 5 % Glucose Intravenous Infusion BP is and what it is used for

5 % Glucose Intravenous Infusion BP is a sterile solution of glucose in water which can either be used to give you fluids and glucose, or can be used as a solution to dissolve other medicines in.5 % Glucose Intravenous Infusion BP will be given to you in the form of a vein drip (that is, by intravenous infusion).

2. What you need to know before you use 5 % Glucose Intravenous Infusion BP

You will not receive 5 % Glucose Intravenous Infusion BP

if you have:
• too high blood sugar level (hyperglycaemia) that needs more than 6 units of insulin per hour to be controlled
• high levels of lactic acid in your blood (lactic acidosis)

You should not receive large amounts of this solution if you have:
• too much water in your body (hypotonic hyperhydration or isotonic hyperhydration)
• acute heart failure (acute congestive heart failure)
• water in your lungs (pulmonary oedema)

5 % Glucose Intravenous Infusion BP must not be used alone for the treatment of fluid deficits, since it does not contain any salts (electrolytes).

Warnings and precautions

Patients who are acutely ill, with pain, postoperative stress, infections, burns, nervous system, heart, liver and kidney diseases and patients who are on medicines increasing the effect of vasopressin (a hormone which regulates the amount of body fluids), when give 5 % w/v Glucose Intravenous

Infusion are at particular risk of developing acute hyponatraemia (abnormally low level of sodium in the blood) which can lead to encephalopathy (brain oedema).
Children, women of childbearing potential and patients with serious brain conditions like meningitis (infection of the membranes surrounding the brain) or brain injury are at particular risk of severe and life-threatening brain swelling caused by an acute decrease in blood sodium levels.
Talk to your doctor, pharmacist or nurse before using 5 % Glucose Intravenous Infusion BP. This medicine must not be used to treat fluid deficits without adequate administration of salts (see also "You will not recieve5 % Glucose Intravenous Infusion BP" above), since this may markedly reduce the salt concentrationin your blood (in particular potassium and sodium). A lack of salts can lead to problems with your heart and damage your brain. Especially children, elderly patients and patients in poor general condition are at risk.
Adequate supply of salts (in particular potassium and sodium) will be ensured. Your levels of blood sugar, fluid, electrolytes (particularly sodium and potassium) and acid-base balance will be checked to make sure that these are correct during infusion. For this purpose blood samples may be taken from you.

If necessary, your blood sugar will be controlled by insulin administration. Your doctor will consider that your blood potassium level may decrease in this case.

Your doctor will consider very carefully whether this medicine is suitable for you if you have:
• diabetes mellitus
• any kind of impairment of your glucose metabolism (e.g. after operations
or injuries)
• impairment of your kidney function.

You should not normally receive this medicine if you suffer or have recently suffered from stroke except if your doctor considers it essential for your recovery. If you are also receiving blood transfusions these will be administered to you through another tube.

Your doctor will consider the safety information of the medicine dissolved or diluted in 5 % Glucose Intravenous Infusion BP.

In some conditions (pain, anxiety, after surgery, nausea, vomiting, fever, sepsis, reduced blood volume, breathing disorders, infections of the central nervous system, metabolism disorders, hormone disorders) the body may produce more of a certain hormone (ADH) which increases water retention. When in addition solutions with only low salt concentrations like this medicine are given, the sodium concentration in the body may become too low (hyponatraemia). This may lead to headache, nausea, seizures, lethargy, coma, swelling of the brain caused by an excess of water (cerebral oedema) and death and is considered a medical emergency.

Children

Since children may have an impaired ability to regulate fluids and electrolytes, special care will be taken when giving this medicine to them.
Body fluid levels, urine production and the electrolyte concentrations in the blood and the urine will be checked carefully.

Other medicines and 5 % Glucose Intravenous Infusion BP

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines especially the following medicines which increase the effect of vasopressin and the risk of a low sodium level (hyponatraemia):
- Carbamazepine and Oxcarbazepine used to treat epilepsy
- Vincristine and ifosfamide used as anticancer treatments

- Cyclophosphamide to treat cancer and autoimmune diseases
- Selective Serotonin Reuptake Inhibitors (SSRIs) to treat depression
- Antipsychotics for mental health disorders
- Opioid pain killers to relieve severe pain
- Non-steroidal anti-inflammatory drugs (NSAIDs) to relieve mild to moderate pain and to treat inflammation in your body,
- Desmopressin for the treatment of diabetes insipidus (extreme thirst and the continuous production of large volumes of dilute urine)
- Oxytocin used during labour
- Vasopressin and terlipressin used to treat 'bleeding oesophageal varices' (enlarged veins in your food pipe caused by liver problems)
- Diuretics or water tablets (medicines which increase the amount of urine)'

Your doctor will consider that some medicines may influence glucose metabolism.

The safety information of the medicine dissolved or diluted in 5 % Glucose Intravenous Infusion BP has to be taken into account.

Pregnancy and breast-feeding

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

Pregnancy

Your doctor will decide carefully whether or not you should receive this solution if you are pregnant.

Breast-feeding

Your doctor will decide carefully whether or not you should receive this solution if you are breast-feeding your child.

Driving and using machines

This medicine has no influence on the ability to drive and use machines.
The safety information of any medicine dissolved or diluted in 5 % Glucose Intravenous Infusion BP has to be taken into account.

3. How to use 5 % Glucose Intravenous Infusion BP

Dosage

The amount of 5% Glucose Intravenous Infusion BP you will be given will be determined by your doctor.

When this medicine is given to you to supply you with fluids, the amount of solution you receive depends on your age, your weight and your medical and physical status. The maximum doses stated below will be considered.

When this medicine is used to dissolve or dilute other medicines given to you, the amount of solution you receive depends on the concentration of the medicine to be dissolved or diluted. The maximum doses stated below will be considered.

Adults

Maximum daily dose

Up to 40 ml per kg body weight per day, corresponding to 2 g glucose per kg body weight per day.

Maximum infusion rate

The maximum infusion rate is 5 ml per kg body weight per hour, corresponding to 250 mg glucose per kg body weight per hour.

The total daily fluid and glucose requirements will be taken into account.

Use in children

If 5 % Glucose Intravenous Infusion BP is given to children, the dose should be as low as possible. Salts have to be supplied as needed. See also section 2, 'Children'.

For **adolescents from 15th year of life,** the maximum amount is 40 ml per kg body weight per day.
For **children up to the 14th year of life** the maximum daily amount of this medicine will be determined according to the age and the body weight:

Premature babies: 180 ml per kg body weight

Newborns: 150 ml per kg body weight
1st – 2nd year: 150 ml per kg body weight
3rd – 5th year: 120 ml per kg body weight
6th – 10th year: 100 ml per kg body weight
11th – 14th year: 80 ml per kg body weight

When determining the dose, the total daily fluid intake will be taken into account, according to the following recommendations for children:

1st day of life: 60 – 120 ml per kg body weight
2nd day of life: 80 – 120 ml per kg body weight
3rd day of life: 100 – 130 ml per kg body weight
4th day of life: 120 – 150 ml per kg body weight
5th day of life: 140 – 160 ml per kg body weight
6th day of life: 140 – 180 ml per kg body weight
1st month, before stable growth: 140 – 170 ml per kg body weight
1st month, with stable growth: 140 – 160 ml per kg body weight
2nd to 12th month of life: 120 – 150 ml per kg body weight
2nd year: 80 – 120 ml per kg body weight
3rd – 5th year: 80 – 100 ml per kg body weight
6th – 12th year: 60 – 80 ml per kg body weight
13th – 18th year: 50 – 70 ml per kg body weight

If you received more 5 % Glucose Intravenous Infusion BP than you should

It is unlikely that this occurs because your doctor will determine your daily doses.

Your doctor will monitor chemical and fluid balance, glucose and electrolyte levels (including sodium) in your blood before and during treatment, especially in patients with disrupted vasopressin release (a hormone which regulates the amount of body fluids) and in patients taking medicines

increasing the action of vasopressin due to the risk of hyponatraemia (abnormal low sodium level in your blood).

Glucose overdose may result in:
• too high levels of blood sugar (hyperglycaemia)
• glucose losses in the urine (glucosuria)
• fluid deficit with abnormally high concentrated body fluids (hyperosmolar dehydration)
• impaired consciousness or unconsciousness due to extremely high blood sugar levels or too concentrated body fluids (hyperglycaemic-hyperosmolar coma)

Fluid overdose may result in excess fluid in the body with:
• increased skin tension
• heaviness and swelling of legs (venous congestion)
• tissue swelling (oedema) possibly with water on the lungs (lung oedema) or swelling of the brain (brain oedema)
• abnormally high or low blood electrolyte levels, so instance low sodium levels (hyponatraemia) or low potassium levels (hypokalaemia)
• disturbances of the acid-base balance

In case of overdose you may feel sick or suffer from vomiting and spasms.

Further signs of overdose may develop depending on the medicine dissolved or diluted in 5 % Glucose Intravenous Infusion BP.

If this occurs, the infusion will be slowed down or stopped.

Your doctor will decide on any further treatment you may need, e.g. administration of insulin, drugs to increase urine output (diuretics) or salts.

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

4. Possible side effects

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

You may develop an imbalance in the level of fluid and of certain minerals in your body. You may develop low sodium (hyponatraemia), potassium, phosphate and magnesium blood levels.

Abnormally low sodium level in your blood can lead to a serious condition called hospital acquired hyponatraemia. It may cause irreversible brain damage and death due to the development of acute hyponatraemic encephalopathy (brain oedema). The symptoms of brain oedema include: headache, feeling sick (nausea), vomiting, seizures, tiredness and lack of energy.

Not known (frequency cannot be estimated from the available data)

- abnormally high or low blood electrolyte levels (salts and minerals in your blood), for instance not enough sodium (hyponatraemia) or not enough potassium (hypokalaemia)

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 the package leaflet. You can also report side effects directly via the Yellow Card Scheme at 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 5 % Glucose Intravenous Infusion BP

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 bottle or the bag and carton labels. The expiry date refers to the last day of that month.

Do not store above 25°C. For storage conditions after admixture of additives see section 6, 'Shelf life after addition of additives'.

Only to be used if solution is clear and colourless or almost colourless and if the container and its closure are undamaged.

The containers are for single use only. Discard container and any remaining contents after use.

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. Other information and content of the pack

What 5 % Glucose Intravenous Infusion BP contains

• The active substance is glucose.
Per litre this medicine contains 55 g of glucose monohydrate, equivalent to 50 g of glucose.
• The other ingredient is water for injections.

Energy	837 kJ/l ≙ 200 kcal/l
Theoretical osmolarity	278 mOsm/l
pH	3.5 – 5.5

What 5 % Glucose Intravenous Infusion BP looks like and contents of the pack

5 % Glucose Intravenous Infusion BP is a solution for infusion (for administration by a vein drip).

It is a clear, colourless or almost colourless solutionof glucose in water.

It comes in:

• colourless plastic (polyethylene) bottles containing 50 ml, 100 ml, 250 ml, 500 ml or 1000 ml,

supplied in packs of: 20 × 50 ml, 20 × 100 ml
20 × 250 ml
10 × 500 ml
10 × 1000 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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The following information is intended for healthcare professionals only:

Incompatibilities
Because 5% Glucose Intravenous Infusion BP has an acidic pH, incompatibilities can occur on mixing with other medicinal products and with blood.
Erythrocyte concentrates must not be suspended in 5% Glucose Intravenous Infusion BP because of the risk of pseudo-agglutination.

Special precautions for disposal and other handling
Administration should commence immediately after connecting the container to the giving set or infusion equipment.Before addition of an additive or preparing a nutrient mixture, physical and chemical compatibility must be confirmed. Because 5% Glucose Intravenous Infusion BP has an acidic pH, incompatibilities can occur on mixing with other medicinal products.
When adding additives observe usual precautions of asepsis strictly.

Shelf life after first opening
Once containers are opened the contents must be used immediately.

Shelf life after addition of additives
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C unless reconstitution / dilution has taken place in controlled and validated aseptic conditions.

For complete information on this medicinal product please refer to the Summary of Product Characteristics.