

## Package leaflet: Information for the patient

### Glucose 20% w/v Solution for Infusion

**Read all of this leaflet carefully before you are 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, 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 Glucose 20% w/v Solution for Infusion is and what it is used for
2. What you need to know before you are given Glucose 20% w/v Solution for Infusion
3. How Glucose 20% w/v Solution for Infusion is given to you
4. Possible side effects
5. How to store Glucose 20% w/v Solution for Infusion
6. Contents of the pack and other information

#### 1. What Glucose 20% w/v Solution for Infusion is and what it is used for

Glucose 20% w/v Solution for Infusion is a sterile solution of glucose in water and is used to:

- restore blood glucose levels.
- provide temporary relief from the symptoms of a swollen brain and comas due to low blood sugar.
- correct high blood potassium levels.

#### 2. What you need to know before you are given Glucose 20% w/v Solution for Infusion

**You should NOT be given Glucose 20% w/v Solution for Infusion if you:**

- are allergic to Glucose 20% w/v Solution for Infusion or any of the other ingredients of this medicine (listed in section 6).
- are allergic to corn or corn products.
- have glucose-galactose malabsorption syndrome.
- have been bleeding in the spine or brain.
- cannot pass urine.
- have had a stroke.
- have a condition known as Delirium Tremens - uncontrolled bouts of shaking after stopping drinking alcohol.

#### Warnings and precautions

**Talk to your doctor, nurse or pharmacist before being given the infusion if you:**

- are a diabetic
- are under-nourished
- have low levels of phosphates (a mineral) or thiamine (vitamin B1) in your blood
- have an infection
- have had a recent injury
- are dehydrated

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 given Glucose 20% w/v Solution for 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.

#### Other medicines and Glucose 20% w/v Solution for Infusion

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



The following information is intended for healthcare professionals only:

### Glucose 20% w/v Solution for Infusion

This is a summary of the information regarding the presentation, preparation and stability of Glucose 20% w/v Solution for Infusion. Please refer to the Summary of Product Characteristics for full prescribing and other information.

#### Presentation:

Glucose 20% w/v Solution for Infusion is a clear and colourless to slightly yellow sterile solution supplied in clear, colourless glass infusion bottles with a nominal value of 100ml.

#### Route of administration:

Intravenous injection or infusion

- Selective Serotonin Reuptake Inhibitors (SSRIs) to treat depression
- The recreational drug 'ecstasy' (MDMA)
- 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)

#### Pregnancy, breast-feeding and fertility

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

#### Driving and using machines

You should not drive or use machinery if you are affected by the administration of Glucose 20% w/v Solution for Infusion.

#### 3. How Glucose 20% w/v Solution for Infusion is given to you

**Your nurse or doctor will give you the infusion.**

Your doctor will decide the correct dosage for you and how and when the infusion will be given.

**If you think you were given more Glucose 20% w/v Solution for Infusion than you should**

Since the infusion will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much, you must tell the person giving you the infusion.

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).

#### 4. Possible side effects

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

- You may suffer from vein clots, inflammation of the veins, local pain at the infusion site.
- You may develop hyperglycaemia (a higher than normal level of sugar in your blood and there may also be sugar in your urine). If this happens you may feel tired and confused or lose consciousness. You may also feel thirsty and pass urine more frequently.
- 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

#### Stability:

From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

#### Special handling information:

Glucose 20% is provided in a concentration that is ready for administration.

Do not use after the expiry date which is stated on the bottle after "EXP". The expiry date refers to the last day of that month.

#### Special precautions for storage:

Do not store above 25°C. Keep the bottle in the outer carton in order to protect from light.

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.

- If you are administered glucose and you have low levels of thiamine (vitamin B1) in your blood you may develop Wernicke's encephalopathy a condition where you may feel confused and unsteady on your feet.
- If you are administered glucose and you are severely under-nourished your body may retain water and salt. Your skin may swell and you may have difficulty in breathing.

### **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 this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 Glucose 20% w/v Solution for Infusion**

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. The expiry date refers to the last day of the month.

Your infusion will be stored at less than 25°C and protected from light. The nurse or doctor will check that the infusion is not past its expiry date before giving you the infusion.

### **6. Contents of the pack and other information**

#### **What Glucose 20% w/v Solution for Infusion contains**

The active substance is glucose (20% w/v or 200 g/l) in a sterile solution.

The other excipients are hydrochloric acid and sterile water for injections.

#### **What Glucose 20% w/v Solution for Infusion looks like and contents of the pack**

Glucose 20% w/v Solution for Infusion is supplied in 100 ml clear glass vials with rubber stopper and cap packed in cartons to contain either 1 vial, 10 vials or 25 vials.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder:**

hameln pharma ltd  
Gloucester  
United Kingdom

#### **Manufacturer:**

Siegfried Hameln GmbH  
Langes Feld 13  
31789 Hameln  
Germany

hameln rds a.s.  
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900 01, Modra,  
Slovak Republic

**For any information about this medicine, please contact the Marketing Authorisation Holder**

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