SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Glucose 20% w/v Solution for Infusion.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml contains 20 g of Glucose EP.

3 PHARMACEUTICAL FORM

Solution for Infusion

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Glucose 20% is hypertonic (*in vitro tonicity*, in a container) and provides a source of calories in a minimal volume of water. Glucose 20% is frequently used in both adults and children to restore blood glucose concentrations in the treatment of hypoglycaemia resulting from insulin excess or from other causes.

Glucose 20% may be used to provide temporary relief from the symptoms of cerebral oedema and from hypoglycaemic coma. Hyperosmotic Glucose with or without insulin may also correct hyperkalaemia in renal failure

4.2 Posology and method of administration

Dosage of Glucose depends on the age, weight, clinical condition of the patient.

Fluid and acid base balance, serum glucose, serum sodium, and other electrolytes may need to be monitored before and during administration, especially in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonists due to the risk of hyponatraemia.

Monitoring of serum sodium is particularly important for physiologically hypotonic fluids (*in vivo* tonicity*)*. Glucose 20 % may become extremely hypotonic after administration due to glucose metabolism in the body (see sections 4.4, 4.5, 4.8 and 5.2).

Posology

Adults and the elderly

For the treatment of hypoglycaemia.
Administer 100 ml of Glucose 20% (at 400 ml/hour over 15 minutes).

As an energy source and in carbohydrate depletion.
Up to 3 Litres per day dependent on the needs of the patient.

Paediatric population

Only to be used under the supervision of a paediatrician

Method of administration

Glucose 20% must be administered by the intravenous route; it must not be administered by subcutaneous or intramuscular route. Except in the emergency treatment of severe hypoglycaemia, Glucose 20% should be administered via a central vein.

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

4.3 Contraindications

Glucose 20% is contraindicated in patients with:

- hypersensitivity to the active substance or to any excipients listed in section 6.1 and known allergy to corn or corn products
- the glucose – galactose malabsorption syndrome
- anuria or intraspinal or intracranial haemorrhage, or ischaemic stroke and in patients with delirium tremens if such patients are already dehydrated
- hyperglycaemic coma.

4.4 Special warnings and precautions for use

Rapid administration of hypertonic glucose solutions may produce substantial hyperglycaemia and hyperosmolar syndrome; patients should be observed for signs of mental confusion and loss of consciousness, especially those patients with chronic uraemia or carbohydrate intolerance.

Prolonged use in parenteral nutrition may affect insulin production; blood and urine glucose should be monitored.

Glucose 20 % intravenous infusion is a hypertonic solution (in vitro, in a container). In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolism (see section 4.2 and 5.2).

Depending on the tonicity of the solution, the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances most importantly hypo- or hyperosmotic hyponatraemia.

Hyponatraemia:
Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns, and CNS disease), patients with heart, liver and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (brain oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain oedema are at particular risk of severe, irreversible and life-threatening brain injury.

Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, and cerebral contusion) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

Intravenous administration of Glucose 20% may result in other electrolyte disturbances such as: hypokalaemia, hypophosphataemia and hypomagnesaemia (see sections 4.2 and 4.8).

Special care should be taken during injection to avoid leakage into the surrounding tissue.

4.5 Interaction with other medicinal products and other forms of interaction

The effects of insulin are reversed by glucose.

Drugs increasing vasopressin effect, listed below, lead to reduced renal electrolyte free water excretion and increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids (see sections 4.2, 4.4 and 4.8):

- Drugs stimulating vasopressin release, e.g.: carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
- Drugs potentiating vasopressin action, e.g.: NSAIDs , cyclophosphamide
- Vasopressin analogues, e.g.: desmopressin, oxytocin, vasopressin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.

4.6 Fertility, pregnancy and lactation

There is no, or inadequate evidence of safety of the drug in human pregnancy, but it has been in wide use for many years without apparent harmful consequence. Intravenous glucose may result in fetal insulin production, with an associated risk of rebound hypoglycaemia in the neonate. Infusions of glucose administered during Caesarean section and labour should be used with caution, and should not exceed 5-10g glucose/hour.

Glucose 20% should be administered with special caution for pregnant women during labour particularly if administered in combination with oxytocin due to the risk of hyponatraemia (see section 4.4, 4.5 and 4.8).

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Very common (≥ 1/10); Common (≥ 1/100 to < 1/10); Uncommon (≥ 1/1,000 to < 1/100); Rare (≥ 1/10,000 to < 1/1,000); Very rare (<1/10,000), Not known (cannot be estimated from the available data)		
System Organ Class (SOC)	Adverse reaction (MedDRA term)	Frequency
Metabolism and nutrition disorders	Hospital acquired hyponatraemia * Hyperglycaemia** Hypokalaemia Hypophosphataemia Hypomagnesaemia Fluid and electrolyte imbalance.	Not known
Nervous system disorders	Hyponatraemic encephalopathy*	Not known
General disorders and administration site conditions	Pain at the injection site Vein irritation Venous thrombosis Phlebitis	Not known

* Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2 and 4.4).

** Hyperglycaemia (possibly indicated by mental confusion or loss of consciousness) and glycosuria may occur as a result of the rate of administration or metabolic insufficiency. If undetected and untreated hyperglycaemia can lead to dehydration, hyperosmolar coma and death.

The administration of glucose without adequate levels of thiamine may precipitate overt deficiency states e.g. Wernicke's encephalopathy. Sodium retention, oedema,

pulmonary oedema and congestive heart failure may be induced in patients with severe under-nutrition.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

Overdose of Glucose 20% may lead to hyperglycaemia and glycosuria leading to dehydration, hyperosmolar coma and death.

The blood levels of glucose can be reduced by slow infusion of insulin. Careful monitoring of blood glucose levels would be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solutions for parenteral nutrition, Carbohydrates
ATC code: B05BA03
The metabolism of glucose is an energy source for the body.

5.2 Pharmacokinetic properties

Glucose is rapidly metabolised into carbon dioxide and water

5.3 Preclinical safety data

No further information other than that which is included in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric Acid

Water for Injections Ph. Eur.

6.2 Incompatibilities

Glucose solutions which do not contain electrolytes, should not be administered concomitantly with blood through the same infusion set, because of the possibilities of agglomeration.

6.3 Shelf life

48 months.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

100ml type I clear colourless glass infusion bottle with rubber stopper and cap, packed in cardboard cartons to contain 1, 10 or 25 vials x 100ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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Nexus, Gloucester Business Park,

Gloucester, GL3 4AG,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 1502/0083

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/06/2013

10 DATE OF REVISION OF THE TEXT

30/10/2024