Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Glucose 5% w/v Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glucose anhydrous..... 50 g/l
As glucose monohydrate..... 55 g/l
Each ml contains 50 mg anhydrous glucose.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.
Clear solution, non coloured to slightly yellow.
Osmolality:..... 300 mosmol/kg
Osmolarity:..... 278 mosmol/l
Carbohydrate caloric content: 200 kcal/l
pH = 3.5 - 6.5

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

This medicine is indicated in the following situations:
- Rehydration when there is loss of water greater than loss of sodium chloride and other osmoles.
- Prevention of dehydration.
- Vehicle for other medicines during the preoperative, peroperative and immediate postoperative periods.
- Prevention and treatment of ketosis during malnutrition.

4.2 Posology and method of administration

Intravenous infusion by peripheral or central vein.
Posology is to be adapted according to patient's clinical status, body weight, diet and any possible other treatments.

Infusion rate must not exceed a volume corresponding to 0.5 g of glucose per minute.
Fluid 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 agonist drugs due to the risk of hyponatraemia.

Monitoring of serum sodium is particularly important for products with lower sodium concentration compared to serum sodium concentration. After infusion of GLUCOSE FRESENIUS 5 %, solution for infusion, a rapid active glucose transport into the body cells occurs. This condition promotes an effect which can be considered as supply of free water and can lead to severe hyponatraemia (see sections 4.4, 4.5 and 4.8).

4.3 Contraindications

Administration of this medicine is contraindicated in the following cases:
- Water overload.
- Glucose intolerance.

4.4 Special warnings and precautions for use

Use a slow infusion rate because of the risk of undesirable osmotic diuresis.
Before use, check that the solution is clear and that the container and its stopper are undamaged; any damage or partially used container must be discarded.

Monitor clinical and laboratory (blood and urine) parameters, in particular water/sodium balance, blood glucose, urinary glucose and acetone, plasma potassium and plasma phosphate.
If necessary, provide parenteral supplements of insulin and potassium.
In diabetics, monitor blood and urinary glucose and possibly adjust the dosage of insulin.
Do not administer blood simultaneously using the same infusion kit because of the risk of pseudo-agglutination.

Intravenous 5% glucose-infusions are isotonic. Glucose solutions with higher glucose concentration are hypertonic. In the body, however, glucose containing fluids can lead to an effect which can be considered as supply of free water due to a rapid active glucose transport into the body cells. This condition can lead to severe hyponatraemia (see section 4.2).
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 diseases), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at particular 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.

Precautions for using bag:

- do not use an air entry;
- flush the infusion system in order to avoid any passage of air.
- do not connect in series since the residual of the first container might be carried on by the solution coming from the second container, with the risk of air embolism.

4.5 Interaction with other medicinal products and other forms of interactions

Drugs leading to an increased vasopressin effect the below listed drugs increase the vasopressin effect, leading 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.: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics.
- Drugs potentiating vasopressin action, e.g.: Chlorpropamide, 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.

Physical-chemical incompatibilities:
It is up to the physician to determine the incompatibility of an added medicine regarding Glucose 5% solution for infusion, by checking for any possible colour change and/or possible formation of precipitate, insoluble complex or crystals. Before adding any medicine, check that the pH range in which it is effective corresponds to that of Glucose 5 % solution for infusion (pH = 3.5 – 6.5). Also check the package leaflet of the medicine to be added. Once a medicine is added to Glucose 5% solution for infusion, the mixture must be administered immediately.

4.6 Fertility, pregnancy and lactation

This product can be used during pregnancy or lactation if necessary.
GLUCOSE FRESENIUS 5 %, solution for infusion should be administrated 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

Not relevant.

4.8 Undesirable effects

System Organ Class	Symptoms (LLT terms MedDRA)	Frequency
Metabolism and nutrition disorders	Hyperglycaemia Hospital acquired hyponatraemia*	Not known
Nervous system disorders	acute hyponatraemic encephalopathy*	
Renal and urinary disorders	Polyuria	
General disorders and administration site conditions	Local site reactions including febrile response, infections at the site of injection, venous thrombosis, phlebitis and extravasation extending from the site of injection	

*Hospital acquired hyponatraemia may cause irreversible brain injury and death, due to development of acute hyponatraemic encephalopathy, frequency unknown (see sections 4.2. 4.4, 4.5).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: + 353 1 6764971; Fax: + 353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

4.9 Overdose

An overdose may lead to hyperosmolarity, dehydration, hyperglycaemia, hyperglycosuria, osmotic diuresis. The treatment is symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

PLASMA SUBSTITUTES AND SOLUTIONS FOR INFUSION/CARBOHYDRATES (ATC Code: B05BA03)
The pharmacological properties of the medicinal product are those of glucose. The caloric intake is 200 kcal/l i.e. 836 kJ/l.
This solution also provide water intake without ionic intake.

5.2 Pharmacokinetic properties

Glucose is metabolised in carbonic gas and water.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection, sodium hydroxide (for pH adjustment), hydrochloric acid, concentrated (for pH adjustment).

6.2 Incompatibilities

Check for any possible change in colour and/or possible formation of precipitate, insoluble complex or crystals. Before adding any medicine, check that the pH zone in which it is effective corresponds to that of Glucose 5 %, solution for infusion (pH = 3.5 – 6.5).
Once a medicine is added to this solution, the mixture must be administered immediately.

6.3 Shelf life

Glass bottles:
Unopened: 5 years
Once opened: Use immediately

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Type II, non coloured glass bottle, closed by chlorobutyl stopper:
1 × 125 ml filled at 50 ml ; 30 ×125 ml filled at 50 ml.
1 × 125 ml filled at 100 ml ; 10 × 125 ml filled at 100 ml ; 30 × 125 ml filled at 100 ml.
1× 125 ml ; 10 × 125 ml ; 30 × 125 ml.
1× 250 ml filled at 125 ml ; 12 × 250 ml filled at 125 ml.
1 × 250 ml ; 10 × 250 ml ; 12 ×250 ml.
1 ×500 ml ; 10 × 500 ml ; 12 × 500 ml.
1 × 1000 ml ; 6 ×1000 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Precautions when using bags:

- do not use an air entry
- flush the infusion system in order to avoid any passage of air.
- for single use only.

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

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1
Bad Homburg v.d.H 61352
Germany

8 MARKETING AUTHORISATION NUMBER

PA2059/040/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th January 2004
Date of last renewal: 28th August 2007

10 DATE OF REVISION OF THE TEXT

September 2019