SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Glucose 10%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml of solution contain

Glucose monohydrate	110.0 g
(Equivalent to anhydrous glucose	100.0 g)

Caloric value	1675 kJ/l ≅ 400 kcal/l
Theoretical osmolarity	555 mOsm/l
Titration acidity (pH 7.4)	< 1 mmol/l
pH	3.5 – 5.5

3. PHARMACEUTICAL FORM

Solution for infusion
Clear, colourless or almost colourless aqueous solution

Total Energy	1675 kJ/l = 400 kcal/l
Theoretical osmolarity	555 mOsm/l
Titration acidity (pH 7.4)	< 1 mmol/l
pH	3.5 – 5.5

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Carbohydrate infusion therapy:

- Hypoglycemic situations
- Hypertonic dehydration
- Hypertonic electrolyte disturbances

Vehicle solution for supplementary medication.

4.2 Posology and method of administration

Dosage

The dosage is to be adjusted according to the individual glucose and fluid requirements.

Dosage for adults, the elderly and adolescents from 15 year of age

The maximum daily dose is 40 ml per kg body weight (BW), corresponding to 4 g of glucose per kg BW.

Note

In the presence of metabolic disorders (e.g. postoperatively or after injuries, hypoxia, organ insufficiencies), the oxidative metabolism of glucose may be impaired. In such situations the glucose intake should be limited to 2 – 4 g/kg BW/day. The blood glucose level should not exceed 6.1 mmol/l (110 mg/100 ml).

The maximum infusion rate is 2.5 ml per kg BW per hour, corresponding to 0.25 g of glucose per kg BW per hour. The maximum drop rate is 0.8 drops per kg BW per minute.

Thus for a patient weighing 70 kg the maximum infusion rate is approx. 175 ml/hour (corresponding maximum drop rate 58 drops/min), resulting in a glucose intake of 17.5 g/hour.

Dosage for Paediatric patients

The daily dose is limited by the maximum fluid intake:

1st day of life:	50-70 ml per kg BW
2nd day of life:	70-90 ml per kg BW
3rd day of life:	80 – 100 ml per kg BW
4th day of life:	100 – 120 ml per kg BW
From 5th day of life:	100 – 130 ml per kg BW
1st year:	100 – 140 ml per kg BW
2st year:	80 – 120 ml per kg BW
3rd –5th year:	80 – 100 ml per kg BW
6th –10th year:	60 - 80 ml per kg BW
11th –14th year:	50-70 ml per kg BW

The corresponding glucose amounts are below the maximum recommended glucose doses for the respective age groups.

If the solution is used as vehicle solution, a volume should be chosen that yields the desired concentration of the medicament to be dissolved or diluted.

Method of administration

Intravenous infusion. The solution can be administered peripherally.
If 10 % w/v Glucose Intravenous Infusion is used as vehicle solution the possibility of peripheral infusion depends on the characteristics of the mixture prepared.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Hyperglycaemia, not responding to insulin doses of up to 6 units insulin/hour
- Decompensated diabetes mellitus, diabetic coma
- Untreated diabetes insipidus
- Acute states of shock or collapse
- Intracranial or spinal haemorrhage
- Metabolic acidosis
- Renal failure (oligo- or anuria) in absence of renal replacement therapy
- Hyperhydration
- Pulmonary oedema
- Acute cardiac failure

4.4 Special warnings and precautions for use

Glucose 10% is a hypertonic solution. In the body, however, glucose containing fluids can become physiologically hypotonic due to rapid glucose metabolization (see section 4.2).

Depending on the tonicity of the solution, 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, postoperative 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.

Administration of glucose solutions is not recommended after acute ischaemic strokes as hyperglycaemia was reported to worsen ischaemic brain damage and impair recovery.

This solution should be used with caution in patients with hypervolemia, renal insufficiency and impending or manifest cardiac decompensation.

The solution should also be administered with caution to patients with increased serum osmolarity.

Disorders of fluid and electrolyte balance like hypotonic dehydration or pathologically low levels of serum electrolytes, must be corrected prior to administration of Glucose 10 % w/v solution for infusion.

Special attention must be paid to hypokalaemia. Then supplementation of potassium is absolutely mandatory.

Unstable metabolism (e.g. postoperatively or after injuries, hypoxia, organ insufficiencies) impairs oxidative metabolism of glucose and may lead to metabolic acidosis.

States of hyperglycaemia should be adequetely monitored and treated with insulin. The application of insulin causes additional shifts of potassium into the cells and may therefore cause or increase hypokalaemia.

Solutions containing glucose should be used with caution in patients with manifest or known subclinical diabetes mellitus or carbohydrate intolerance for any reason.

Profound hypoglycemia may follow sudden discontinuation of high glucose infusion rates because of the accompanying high serum insulin concentrations. This applies especially to children less than 2 years of age, patients with diabetes mellitus and other disease states with impaired glucose homeostasis. In obvious cases the glucose infusion should be tapered off within the last 30 –60 minutes of the infusion. As a precaution it is recommended that each individual patient be monitored for 30 minutes for hypoglycemia on the first day of abrupt discontinuation of parenteral nutrition.

Refeeding or repletion of malnourished or depleted patients may in particular cause hypokalaemia, hypophosphataemia and hypomagnesaemia. Adequate supplementation of electrolytes according to deviations from normal values is necessary.

Clinical monitoring should include blood glucose, serum electrolytes, fluid and acid-base balance in general. Frequency and kind of laboratory testing depend on the overall condition of the patient, the prevailing metabolic situation and the administered dose. Also monitor total volume and amount of glucose administered.

Electrolytes and vitamins should be supplied as necessary. Vitamin B, especially thiamine, is needed for glucose metabolism.

Glucose infusions should not be administered through the same infusion equipment, simultaneously with, before, or after administration of blood, because of the possibility of pseudo-agglutination.

4.5 Interactions with other medicinal products and other forms of interaction

Interactions with medicinal products with an influence on glucose metabolism should be considered.

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.

Prescribers should refer to the information provided with the product concerned.

4.6 Pregnancy and lactation

For 10 % w/v glucose solutions for infusion no controlled clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foeta1development, parturition or postnatal development.

Yet caution should be exercised when prescribing to pregnant or nursing women and careful monitoring of blood glucose is necessary.

Glucose 10% 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

No effects to be expected.

4.8 Undesirable effects

Provided the product is used in accordance with the directions given, undesirable effects are not to be expected.

The following side effects, which are not directly related to the product but to the conditions of administration, underlying disorders or accompanying treatment, may occur:

Metabolism and nutrition disorders
Not known: Hospital Acquired Hyponatraemia

– Hypokalemia may be related to insulin therapy. In addition, hypokalaemia, hypomagnesaemia and hypophosphataemia may be caused by refeeding with glucose especially in malnourished patients.
– Abrupt discontinuation and/or insulin application may cause rebound hypoglycemia, especially in patients with glucose tolerance disorders.

Neurological disorders :
Not known: Hyponatraemic encephalopathy

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

Vascular disorders
Thrombophlebitis may be caused by osmolarities above 800 mmol/l. The osmolarity of the added medication should be kept in mind.

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form (https://sideeffects.health.gov.il)

4.9 Overdose

Symptoms

Overdose may cause hyperglycaemia, glucosuria, serum hyperosmolarity, possibly leading to hyperosmotic and hyperglycaemic coma, further hyperhydration and electrolyte disorders.

Emergency treatment, antidotes

The disorders mentioned above can be corrected by reduction of the glucose intake, administration of insulin and/or appropriate supplementation of electrolytes.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmaco-therapeutic group:
Solutions for parenteral nutrition, carbohydrates, ATC code: B05B A03

Glucose is metabolised ubiquitously as the natural substrate of the cells of the body. Under physiological conditions glucose is the most important energy-supplying carbohydrate with a caloric

value of approx. 17 kJ/g or 4 kcal/g. Nervous tissue, erythrocytes and the medulla of the kidneys are amongst the tissues with an obligate requirement for glucose. In adults, the normal concentration of glucose in blood is 60 – 100 mg/100 ml, or 3.3 – 5.6 mmol/l (fasting).

Glucose serves to maintain the blood glucose level and for the synthesis of important body components. It serves for the synthesis of glycogen, the storage form of glucose. Primarily insulin, glucagon, glucocorticosteroids and catecholamines are involved in the regulation of the blood glucose concentration.

A normal electrolyte and acid-base status is a prerequisite for the optimal utilisation of administered glucose. So acidosis, in particular, can indicate impairment of oxidative glucose metabolism.

Metabolism of glucose and electrolytes are closely related to each other. Potassium, magnesium and phosphate requirements may increase and may therefore have to be monitored and supplemented according to individual needs. Especially cardiac and neurological functions may be impaired without supplementation.

Glucose intolerance may occur under pathological conditions, e.g. diabetes mellitus and metabolic stress (e.g. intra-, and postoperatively, severe disease, injury, sepsis). Severity of hyperglycaemia and glucosuria are related to the severity of the pathological state.

Infusion of higher concentrated glucose solutions can aggravate brain damage and cerebral oedema in cases of head injury, cerebrovascular accidents and ischemia.

5.2 Pharmacokinetic properties

On infusion glucose is first distributed in the intravascular space and then is taken up into the intracellular space.

In glycolysis, glucose is metabolised to pyruvate or to lactate. Lactate can be partially re-introduced into the glucose metabolism (Cori cycle). Under aerobic conditions pyruvate is completely oxidised to carbon dioxide and water. The final products of the complete oxidation of glucose are eliminated via the lungs (carbon dioxide) and the kidneys (water).

Practically no glucose is excreted renally by healthy persons. In pathological metabolic conditions (e.g. diabetes mellitus, postaggression metabolism) associated with hyperglycaemia, glucose is also excreted via the kidneys (glucosuria) when the maximum tubular resorption capacity (at blood glucose levels higher than 180 mg/100 ml or 10 mmol/l) is exceeded.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to the safety instructions already stated in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

Because of its acid pH, the solution may be incompatible with other medicaments.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Polyethylene bottles,
contents: 500 ml, 1000 ml

6.6 Special precautions for disposal

Single-dose container. Discard unused contents.
Only to be used if the solution is clear and the container or its closure do not show visible signs of damage.

7. MANUFACTURER

B.Braun Melsungen AG,
Carl-Braun str.1,D-34212, Melsungen, Germany

8. REGISTRATION HOLDER

Lapidot Import and Marketing Ltd.
8 Hashita St., Industrial Park, Caesarea 3088900, ISRAEL

9. MARKETING AUTHORISATION NUMBER

116-96-27991-00

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