SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<TRADE NAME> 10% Solution for Infusion

<REGARDING THE APPROVAL>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 10% w/v of glucose.

For the full list of excipients, see section 6.1.

<REGARDING THE APPROVAL>

1. PHARMACEUTICAL FORM

Solution for Infusion

<REGARDING THE APPROVAL>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

10% glucose solution is indicated for supplemental intravenous nutrition as a preferred source of carbohydrate.

* 1. Posology and method of administration

For intravenous infusion under medical supervision, via a central venous catheter. If a peripheral vein has to be used in emergency situations, the solution should be given slowly and the site should be alternated regularly.

Single use only.

The volume of 10% glucose solution needed as supplemental nutrition will vary with patient age, body weight, complementary treatment and severity of the clinical condition. These factors should be taken into account during infusion therapy. There is no recommended dose as this is a matter for clinical judgment and laboratory assessment in each case.

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 physiologically hypotonic fluids. Glucose 10% Intravenous Infusion may become extremely hypotonic after administration due to glucose metabolization in the body (see sections 4.4, 4.5 and 4.8).

* 1. Contraindications

Conditions of water excess. The use of hyperosmotic glucose solutions is contraindicated in patients with anuria, intracranial or intraspinal haemorrhage, and in delirium tremens where there is dehydration.

Hyperglycaemia resulting from infusion with glucose solutions following acute ischaemic stroke is implicated in increasing cerebral ischaemic brain damage and impaired recovery..

* 1. Special warnings and precautions for use

Do not use after date of expiry printed on the bag

* Do not use unless the solution is clear and the container undamaged
* Confirm additive compatibility before use
* Discard any unused solution
* Infusion rate should be sufficiently slow to allow detection of osmotic diuresis
* Glucose infusions are incompatible with blood for transfusion as haemolysis and clumping may occur; do not administer through the same infusion equipment as blood or blood components for transfusion (either before, during or after their administration).
* If more than 180g glucose is given per day (equivalent to 1.8 litres) frequent monitoring of blood glucose is required and insulin may be necessary.
* Prior to and during infusion serum and/or urinary electrolytes and glucose should be monitored to assess the nature and severity of fluid depletion and electrolyte imbalance. Close monitoring of patients with diabetes mellitus, and in patients with renal failure, is necessary during glucose infusion.
* Use with caution in severe malnutrition (when glucose infusion can cause sodium retention, oedema and heart failure), and in thiamine deficiency. In patients with hepatic failure, excessive glucose infusion may be detrimental in portasystemic encephalopathy.
* Glucose intravenous infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization (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.

* 1. Interaction with other medicinal products and other forms of interaction

**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.

Confirm additive compatibility before use. See section 6.2 Incompatibilities.

* 1. Fertility, pregnancy and lactation

It is particularly important to avoid maternal hyperglycaemia during intravenous glucose infusion in the perinatal period in view of the possibility of inducing neonatal hypoglycaemia.

Glucose 10% Intravenous 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 sections 4.4, 4.5 and 4.8).

* 1. Effects on ability to drive and use machines

Not relevant.

* 1. Undesirable effects

Hypertonic glucose solutions may have a low pH and may cause venous irritation, local pain and thrombophlebitis. Intravenous infusion of glucose solutions can lead to the development of fluid and electrolyte disturbances including hypokalaemia, hypomagnesaemia and hypophosphataemia. Hypokalaemia may complicate glucose infusions, especially when combined with insulin in the treatment of diabetic ketoacidosis. Hypophosphataemia may occur if glucose is used as a feed without added phosphate.

Metabolism and nutrition disorders: Hospital Acquired Hyponatraemia\* (frequency not known).

Nervous system disorders: Hyponatraemic encephalopathy\* (frequency 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).

In the event of adverse reaction stop infusion immediately.

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 Health Product Vigilance Center; HPVC

* 1. Overdose

Severe over-infusion may cause plasma hyperosmolality and osmotic diuresis. Prolonged or rapid administration of hyperosmotic solutions may result in hyperglycaemia and dehydration. Treatment is symptomatic.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

Pharmacotherapeutic group: electrolyte with carbohydrate, ATC code: B05BB02

Glucose is rapidly absorbed into cells and metabolized into carbon dioxide and water with the release of energy. 10% glucose solution allows cellular rehydration and glucose serves as a preferred source of carbohydrate for cellular nutrition.

* 1. Pharmacokinetic properties

The maximum rate of glucose utilization has been estimated to be about 500-800 mg/ kg body weight /hour.

* 1. Preclinical safety data

None stated.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<REGARDING THE APPROVAL>

* 1. Incompatibilities

The compatibility of additives must be confirmed before use.

* 1. Shelf life

<REGARDING THE APPROVAL>

* 1. Special precautions for storage

<REGARDING THE APPROVAL>

* 1. Nature and contents of container

<REGARDING THE APPROVAL>

* 1. Special precautions for disposal

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION HOLDER

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION NUMBER(S)

<REGARDING THE APPROVAL>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<REGARDING THE APPROVAL>

1. DATE OF REVISION OF THE TEXT1

<REGARDING THE APPROVAL>