Summary of Product Characteristics

1. Name of the medicinal product
Glucose 50% w/v Concentrate for solution for infusion.

2. Qualitative and quantitative composition
Anhydrous Glucose 50 %w/v equivalent to orGlucose Monohydrate

3. Pharmaceutical form
Solution for infusion

Description: Clear, colorless solution.

Glucose 50% w/v has an osmolality of 2775 mOsmol/L.

4. Clinical particulars

4.1. Therapeutic indications
Glucose 50% w/v is for use in admixtures to provide temporary relief from the symptoms of increased intracranial pressure and hypoglycemic coma and is also indicated for the supplementation of energy in parenteral nutrition.

4.2. Posology and method of administration

Posology
The dosage and rate of administration of Glucose 50% w/v are determined by several factors including theindication for use and the patient's age, weight and clinical condition.

Method of administration
Glucose 50% w/v is for administration by intravenous infusion following appropriate dilution or incorporation in to a parenteral nutrition admixture.

Administration of hyperosmolar solutions may cause venous irritation and phlebitis.

The resultant admixture should be administered through a central or peripheral venous line depending on its final osmolality. If the final mixture, to be administered, is hypertonic it may cause irritation of the vein when administered into a peripheral vein.

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, as well as concomitant therapy.

A gradual increase of flow rate should be considered when starting administration of glucose -containingproducts.

To reduce the risk of hypoglycemia after discontinuation, a gradual decrease in flow rate before stopping the infusion should be considered.

Electrolyte supplementation may be indicated according to the clinical needs of the patient.
As indicated on an individual basis, vitamins and trace elements and other components (including amino acids and lipids) can be added to the parenteral regimen to meet nutrient needs and prevent deficiencies and complications from developing.

Dilute Glucose 50% w/v before use to a concentration which will, when administered with an amino acid (nitrogen) source, result in an appropriate calorie to gram of nitrogen ratio and which has an osmolality consistent with the route of administration.

When Glucose 50% w/v is used in conjunction with amino acids, the rate of administration of glucoseshould not exceed 1g/kg/hour for optimal protein anabolism.
Use in Pediatric Patients

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in pediatric intravenous fluid therapy (see section 4.4).

4.3. Contraindications

Contra-indicated in patients with:
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. See sections 4.4 and 4.8 for corn allergies.
- Clinically significant hyperglycemia

4.4. Special warnings and precautions for use

WARNINGS
Not for direct intravenous infusion. Must be appropriately diluted before use. The admixture obtained should be administered through a central or peripheral venous line depending on its final osmolarity.

Unless appropriately diluted infusion of hypertonic glucose solutions into a peripheral vein may result in vein irritation, vein damage, and thrombosis. Strongly hypertonic solutions should only be administered through an indwelling intravenous catheter with the tip located in a large vein such as the superior vena cava.

Prolonged intravenous infusion of this solution may cause thrombophlebitis extending from the site ofinfusion.

Dilution and other effects on serum electrolytes
Depending on 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:
- Hyper osmolality, osmotic diuresis and dehydration
- Hypo osmolality
- Electrolyte disturbances such as:
- hyponatremia (see below),
- hypokalemia,
- hypophosphatemia,
- hypomagnesaemia,
- over hydration/hypervolemia and, for example, congested states, including pulmonary congestion andoedema.
-

The above effects do not only result from the administration of electrolyte-free fluid but also from glucoseadministration.

Hyponatremia can develop into acute hyponatremia encephalopathy characterized by headache, nausea, seizures, lethargy, coma, cerebral oedema, and death.
Children, the elderly, women, postoperative patients, patients with hypoxia and patients with central nervous system disease or psychogenic polydipsia are at particular risk for this complication.

Clinical evaluation and periodic laboratory determinations may be necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

Particular caution is advised in patients at increased risk of water and electrolyte disturbances that could be aggravated by increased free water load, hyperglycemia or possibly required insulin administration (see below).

Hyperglycemia
As with the intravenous administration of nutrients (e.g., glucose, amino acids and lipids) in

general, metabolic complications may occur if the nutrient intake is not adapted to the patient's requirements, or the metabolic capacity of any given dietary component is not accurately assessed. Adverse metabolic effects may arise from administration of inadequate or excessive nutrients or from inappropriate composition of an admixture for a particular patient's needs.

Rapid administration of glucose solutions may produce substantial hyperglycemia and a hyperosmolarsyndrome.

To reduce the risk of hyperglycemia-associated complications, the infusion rate must be adjusted and/or insulin administered.

Intravenous glucose should be administered with caution in patients with, for example:
- impaired glucose tolerance (such as in patients with renal failure or diabetes mellitus, or in the presence of sepsis, trauma, or shock),
- severe malnutrition (risk of precipitating a refeeding syndrome),
- thiamine deficiency, e.g., in patients with chronic alcoholism (risk of severe lactic acidosis due toimpaired oxidative metabolisation of pyruvate),
- water and electrolyte disturbances that could be aggravated by increased glucose and/or free waterload (see above).
-
- patients with ischemic stroke or severe traumatic brain injury
- avoid infusion within the first 24 hours following head trauma. Monitor blood glucose closely as early hyperglycemia has been associated with poor outcomes in patients with severe traumatic brain injury.
- newborns (see below).

Effects on Insulin Secretion
Prolonged intravenous administration of glucose and associated hyperglycemia may result in decreased rates of glucose-stimulated insulin secretion.

Hypersensitivity Reactions
Hypersensitivity/infusion reactions, including anaphylactic/anaphylactoid reactions, have been reported (seesection 4.8).

Solutions containing glucose should be used with caution, if at all, in patients with known allergy to corn or corn products. The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develops.
Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Refeeding syndrome
Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intakes while avoiding overfeeding can prevent these complications.

Liver disorders
Hepatobiliary disorders including cholestasis, hepatic steatosis, fibrosis and cirrhosis, possibly leading to hepatic failure, as well as cholecystitis and cholelithiasis are known to develop in some patients on parenteral nutrition. The etiology of these disorders is thought to be multifactorial and may differ between patients.

Patients developing abnormal laboratory parameters or other signs of hepatobiliary disorders should be assessed early by a clinician knowledgeable in liver diseases in order to identify possible causative and contributory factors, and possible therapeutic and prophylactic interventions.

Catheter infection and sepsis
Infection and sepsis may occur as a result of the use of intravenous catheters to administer parenteral formulations, poor maintenance of catheters or contaminated solutions.

Immunosuppression and other factors such as hyperglycemia, malnutrition and/or their underlying disease state may predispose patients to infectious complications.

Careful symptomatic and laboratory monitoring for fever/chills, leukocytosis, technical complicationswith the access device, and hyperglycemia can help recognize early infections.

The occurrence of septic complications can be decreased with heightened emphasis on aseptic technique in catheter placement, maintenance, as well as aseptic technique in nutritional formula preparation.

Precipitates
Pulmonary vascular precipitates have been reported in patients receiving parenteral nutrition. In some cases, fatal outcomes have occurred. Excessive addition of calcium and phosphate increases the risk of the formation of calcium phosphate precipitates. Precipitates have been reported even inthe absence of phosphate salt in the solution.

In addition to inspection of the solution, the infusion set and catheter should also periodically be checked for precipitates. If signs of pulmonary distress occur, the infusion should be stopped and medical evaluation initiated.

Pediatric population
The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy, and should be determined by a consulting physician experienced in pediatric intravenous fluid therapy.

In order to avoid potentially fatal over infusion of intravenous fluids to the neonate, special attention needs to be paid to the method of administration. When using a syringe pump to administer intravenous fluids or medicines to neonates, a bottle of fluid should not be left connected to the syringe.

When using an infusion pump all clamps on the intravenous administration set must be closed before removing the administration set from the pump, or switching the pump off. This is required regardless of whether the administration set has an anti-free flow device.

The intravenous infusion device and administration equipment must be frequently monitored.

Pediatric glycaemia related issues
Newborns, especially those born premature and with low birth weight - are at increased risk of developing hypo- or hyperglycemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycemic control in order to avoid potential long term adverse effects.

Hypoglycemia in the newborn can cause prolonged seizures, coma and brain damage. Hyperglycemia has been associated with intraventricular hemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitits, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

Pediatric hyponatremia-related issues
Children (including neonates and older children) are at increased risk of developing hypo osmotic hyponatremia as well as for developing hyponatremia encephalopathy.

Plasma electrolyte concentrations should be closely monitored in the pediatric population.
Rapid correction of hypo osmotic hyponatremia is potentially dangerous (risk of serious neurologiccomplications). Dosage, rate, and duration of administration should be determined by a physician experienced in pediatrics intravenous fluid therapy.

Geriatric Use
When selecting the type of infusion solution and the volume/rate of infusion for a geriatric patient, consider that geriatric patients are generally more likely to have cardiac, renal, hepatic impairment,

andother diseases or concomitant drug therapy.

Blood
Glucose solution (an aqueous, i.e., electrolyte-free glucose solution) should not be administered through the same equipment as whole blood, as hemolysis and pseudo agglutination can occur.

4.5. Interaction with other medicinal products and other forms of interaction

Both the glycemic effects of intravenous glucose and its effects on water and electrolyte balance should be taken into account when using intravenous glucose in patients treated with other substances that affect glycemic control, or fluid and/or electrolyte balance.

4.6. Fertility, pregnancy and lactation

Intrapartum maternal intravenous glucose infusion may result in foetal insulin production, with an associated risk of foetal hyperglycemia and metabolic acidosis as well as rebound hypoglycemia in theneonate.

Pregnancy
Glucose solution can be used during pregnancy. However, caution should be exercised when glucose solution is used intrapartum.

Fertility
There are no adequate data of the effect of Glucose on fertility.

Lactation
There are no adequate data of using Glucose solution during lactation. Glucose solutions have been used during lactation.

4.7. Effects on ability to drive and use machines

There is no information on the effects of intravenous glucose on the ability to operate a vehicle or otherheavy machinery.

4.8. Undesirable effects

The following adverse reactions have been reported in the post-marketing experience

System Organ Class	***Adverse reaction***	***Frequency****
Immune system disorders	Anaphylactic reaction**	Not known
	Hypersensitivity**	Not known

Metabolism and nutrition disorders	Hyperglycemia	Not known
Skin and subcutaneous tissue disorders	Rash	Not known
General disorders and administration site conditions	Chills	Not known
	Pyrexia	Not known
	Infection at site of injection	Not known
	Thrombophlebitis	Not known
	Infusion site reactions including, • Infusion site phlebitis • Infusion site erythema	Not known

* Cannot be estimated from the available data
** Potential manifestation in patients with allergy to corn, see section 4.4. Other adverse reactions reported with glucose injection/infusions include:
- Hyponatremia, which may be symptomatic
- Infusion site thrombophlebitis (associated with hyperosmolar solutions)
- Adverse reactions reported when glucose is used with parenteral nutrition:

- Hepatic failure, Hepatic cirrhosis, Hepatic fibrosis, Cholestasis, Hepatic steatosis, Blood bilirubin increased, Hepatic enzyme increased, Cholecystitis, Cholelithiasis
- Pulmonary vascular precipitates

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization 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.

4.9. Overdose

Prolonged administration or rapid infusion of large volumes of the product may cause hyperosmolarity and hyponatremia, dehydration, hyperglycemia, hyperglycosuria, osmotic diuresis (due to hyperglycemia) and water intoxication and oedema. Severe hyper glycaemia and hyponatremia may be fatal (see sections 4.4 and 4.8).

In case of suspected overdose, treatment must be stopped immediately. Management of overdose issymptomatic and supportive, with appropriate monitoring.'

5. Pharmacological properties
2. Pharmacodynamic properties

Not applicable.

3. Pharmacokinetic properties

Not applicable.

4. Preclinical safety data

Not applicable.

6. Pharmaceutical particulars
2. List of excipients

Water for Injections

3. Incompatibilities

This solution should not be used in conjunction with additives incompatible with glucose, see section 6.6.

4. Shelf life

Unopened: 24 months
It is recommended that the product is used immediately after opening the bottle. From a microbiological point of view, any admixture should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C. Preparation of the admixture should take place under controlled and validated asepticconditions.

5. Special precautions for storage

Store below 30°C.protect from light
For further information, see section 6.3.

6. Nature and contents of container

Bottle size:100 mL
The bottle is made of polypropylene granules.

Pack sizes:
- 28 bottles of 100 ml per carton
- 24 bottles of 100 ml per carton

7. Special precautions for disposal and other handling

Dilution or addition to parenteral nutrition admixtures must take place in controlled and validated aseptic conditions.

The product should be inspected visually for particulate matter and discoloration after admixing and prior to administration. Do not administer unless the solution is clear and theseal is intact.
Check compatibility with other admixture components before use.

Additives known or determined to be incompatible with glucose as a diluent should not be used. Theinstructions for use of the medication to be added, including information on storage, must be consulted.

Before adding a substance or medication, verify that it is soluble and/or stable in water and that thepH range of the glucose solution is appropriate.

Mix the solution thoroughly when additives have been introduced.
Use of an in-line filter is recommended during administration of all parenteral solutions where possible. Single use only.

Do not store partially used bottles.
Discard any unused portion, waste materials and all associated devices.

7. Marketing Authorization Holder

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8. Marketing authorization number(s)

TAN 22 HM 0198

9. **Date of first authorization/renewal of the authorization**
   04/05/2022

10. **Date of Revision of the Text**