1. NAME OF THE MEDICINAL PRODUCT

10% Dextrose intravenous infusion BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Glucose (as Anhydrous): 10.0g

Each 100ml contains 10.0g glucose equivalent to glucose anhydrous BP.

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL form

Solution for infusion

Clear solution, free from visible particles

4. Clinical particulars

4.1 Therapeutic indications

10% Dextrose is indicated for the treatment of carbohydrate and fluid depletion.

10% Dextrose is also used as a vehicle and diluent for compatible medicinal products for parenteral administration.

4.2 Posology and method of administration

Posology

Adults, the Elderly and Children:

The concentration and dosage of glucose solution for intravenous use is determined by several factors including the age, weight and clinical condition of the patient. Serum-glucose concentrations may need to be carefully monitored.

The recommended dosage for treatment of carbohydrate and fluid depletion is:

- for adults: 500 ml to 3 litres / 24h

- for babies and children :

- 0-10 kg body weight:	100 ml/kg/24h.
- 10-20 kg body weight:	1000 ml + 50 ml /kg over 10 kg / 24h.
- > 20 kg body weight:	1500 ml + 20 ml / kg over 20 kg / 24h.

The infusion rate depends on the patient's clinical condition.

Infusion rate should not exceed the patient's glucose oxidation capacities in order to avoid hyperglycaemia. Therefore, the maximum dose ranges from 5mg/kg/min for adults to 10-18 mg/kg/min for babies and children depending on the age and the total body mass.

The recommended dosage when used as a vehicle or diluent ranges from 50 to 250 ml per dose of medicinal product to be administered.

When 10% Dextrose is used as a diluent for injectable preparations of other drugs, the dosage and the infusion rate will be principally dictated by the nature and the dose regimen of the prescribed drug.

Paediatric 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 the consulting physician experienced in paediatric intravenous fluid therapy.

Method of administration:

The solution is for administration by intravenous infusion (peripheral or central vein).

When the solution is used for dilution and delivery of therapeutic additives for administration by intravenous infusion, the direction for use with additive therapeutic substances will dictate the appropriate volumes for each therapy.

10% Dextrose intravenous infusion is a isosmotic solution.

Please see section 3 for the information about the osmolarity of the solution.

Precautions to be taken before handling or administering the medicinal product

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Use only if the solution is clear, without visible particles and the container is undamaged. Administer immediately following the insertion of infusion set.

The solution should be administered with sterile equipment using aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

Electrolyte supplementation may be indicated according to the clinical needs of the patient.

Additives may be introduced before or during infusion through the injection site.

When introducing additives, the final osmolarity of solutions need to be checked. Administration of hyperosmolar solutions may cause venous irritation and phlebitis. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.

Please see section 4.4 for the risk of air embolism.

4.3 Contraindications

The solution is contraindicated in case of uncompensated diabetes, other known glucose intolerances (such as metabolic stress situations), hyperosmolar coma, hyperglycaemia, hyperlactataemia.

Hypersensitivity to the active substance. See sections 4.4 and 4.8 for corn allergies.

4.4 Special warnings and precautions for use

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:

• Hyperosmolality, osmotic diuresis and dehydration

• Hypoosmolality

• Electrolyte disturbances such as

- hyponatraemia (see below),

- hypokalaemia,

- hypophosphataemia,

- hypomagnesaemia,

- overhydration/hypervolaemia and, for example, congested states, including pulmonary congestion and oedema.

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

Hyponatraemia can develop into acute hyponatraemic 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, hyperglycaemia or possibly required insulin administration (see below).

Hyperglycaemia

• Rapid administration of glucose solutions may produce substantial hyperglycaemia and a hyperosmolar syndrome.

• If hyperglycaemia occurs, rate of infusion should be adjusted and/or insulin administered

• If necessary, provide parenteral supplements in potassium.

• Intravenous Glucose 10% should be administered with caution in patients with, for example:

- impaired glucose tolerance (such as in diabetes mellitus, renal failure, or in the presence of sepsis, trauma, or shock),

- severe malnutrition (risk of precipitating a refeeding syndrome – see below),

- thiamine deficiency, e.g., in patients with chronic alcoholism (risk of severe lactic acidosis due to impaired oxidative metabolization of pyruvate),

- 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 hyperglycaemia has been associated with poor outcomes in patients with severe traumatic brain injury.

- newborns

Effects on Insulin Secretion

Prolonged intravenous administration of glucose and associated hyperglycaemia may result in decreased rates of glucose-stimulated insulin secretion.

Hypersensitivity Reactions

• Hypersensitivity/infusion reactions, including anaphylactic/anaphylactoid reactions, have been reported with Glucose solutions (see section 4.8). Solutions containing glucose should therefore be used with caution, if at all, in patients with known allergy to corn or corn products (see section 4.3).

• The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. 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.

Paediatric 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 paediatric 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 bag 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.

Paediatric glycaemia-related issues

Newborns – especially those born premature and with low birth weight - are at increased risk of developing hypo- or hyperglycaemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycaemic control in order to avoid potential long term adverse effects. Hypoglycaemia in the newborn can cause prolonged seizures, coma and cerebral injury. Hyperglycaemia has been associated with intraventricular haemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

Paediatric hyponatraemia-related issues

• Children (including neonates and older children) are at increased risk of developing hypoosmotic hyponatraemia as well as for developing hyponatraemic encephalopathy.

• Plasma electrolyte concentrations should be closely monitored in the paediatric population.

• Rapid correction of hypoosmotic hyponatraemia is potentially dangerous (risk of serious neurologic complications).

• Dosage, rate, and duration of administration should be determined by a physician experienced in paediatric 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, and other diseases or concomitant drug therapy.

Blood

• Glucose 10% (an aqueous, i.e., electrolyte-free glucose solution) should not be administered simultaneously with, before or after an administration of blood through the same infusion equipment, because haemolysis and pseudoagglutination can occur.

Adding other medication or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of adverse reaction, infusion must be stopped immediately.

Risk of Air Embolism

• Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.

• Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

• Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

4.5 Interaction with other medicinal products and other forms of interaction

Both the glycemic effects of 10% Detrose and its effects on water and electrolyte balance should be taken into account when using Glucose 10% in patients treated with other substances that affect glycaemic control, or fluid and/or electrolyte balance.

Concomitant administration of catecholamines and steroids decreases the glucose up-take.

No interaction studies have been performed.

4.6 Pregnancy and lactation

When a medicinal product is added, the nature of the drug and its use during pregnancy and lactation have to be considered separately.

Intrapartum maternal intravenous glucose infusion may result in foetal insulin production, with an associated risk of foetal hyperglycaemia and metabolic acidosis as well as rebound hypoglycaemia in the neonate.

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 10% on fertility. However, no effect on fertility is expected.

Lactation

There are no adequate data of using Glucose solution during lactation. However, no effect on lactation is expected. Glucose 10% can be used during lactation.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Undesirable effects which occurred in patients treated with Glucose 10% from the post-marketing experience are tabulated below.

The adverse drug reactions listed in this section are given following the recommended frequency convention: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000); and not known (cannot be estimated from the available data).

	Tabulated list of adverse reactions	
System Organ Class	*Adverse reaction (MedDRA term)*	*Frequency*
Immune system disorders	Anaphylactic reaction* Hypersensitivity*	Not known
Metabolism and nutrition disorders	Electrolyte imbalance Hypokalaemia Hypomagnesaemia Hypophosphatemia Hyperglycaemia Dehydration Hypervolaemia	Not known
Skin and subcutaneous tissue disorders	Rash	Not known
Vascular disorders	Venous thrombosis Phlebitis	Not known
Renal and urinary disorders	Polyuria	Not known
General disorders and administration site conditions	Chills* Pyrexia* Infusion site infection Infusion site irritation for example erythema Extravasation Local reaction Pain localised	Not known

*Potential manifestation in patients with allergy to corn, see section 4.4.

Other adverse reactions reported with glucose injection/infusions include:

Hyponatraemia, which may be symptomatic

4.9 Overdose

Prolonged administration or rapid infusion of large volumes of Glucose 10% may cause hyperosmolarity and hyponatraemia, dehydration, hyperglycaemia, hyperglycosuria, osmotic diuresis (due to the

hyperglycaemia) and water intoxication and oedema. Severe hyperglycaemia and hyponatraemia may be fatal (see sections 4.4 and 4.8).

In case of suspected overdose, treatment with Glucose 10% must be stopped immediately. Management of overdose is symptomatic and supportive, with appropriate monitoring.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: “Other IV Solution Additives”

ATC code: B05BA03

The pharmacodynamic properties of this solution are those of glucose, which forms the principal source of energy in cellular metabolism. Glucose 10% is given as a source of carbohydrate in parenteral nutrition. The Glucose 10% solution provides a caloric intake of 200 kcal/l. Furthermore, this glucose solution for infusion allows hydric supplementation without ionic supplementation.

Glucose 10% is a isosmotic solution, with an approximate osmolarity of 278 mOsm/l.

The pharmacodynamics of the additive will depend on the nature of the drug used.

5.2 Pharmacokinetic properties

Glucose is metabolized via pyruvic or lactic acid to carbon dioxide and water with the release of energy.

The pharmacokinetics of the additive will depend on the nature of the drug used.

5.3 Preclinical safety data

The safety of glucose in animals is not relevant in view of its presence as a normal component in animal and human plasma.

The safety of the additive should be considered separately.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Not Applicable

6.2 Incompatibilities

As with all parenteral solutions compatibility of the additives with the solution must be assessed before addition.

It is the responsibility of the physician to judge the incompatibility of an additive medication with the Glucose 10% solution by checking for eventual colour change and/or eventual precipitate, insoluble complexes or crystals apparition. The Instructions for Use of the medication to be added must be consulted.

Before adding a drug, verify it is soluble and stable in water at the pH of Glucose 10%.

When a compatible medication is added to the Glucose 10%, the solution must be administered immediately.

Those additives known to be incompatible should not be used.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

500ml in a Low Density Polyethylene

6.6 Special precautions for disposal <and other handling>

Discard after single use.

Discard any unused portion.

Do not store solutions containing additives.

Do not reconnect partially used bags.

Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the product.

When introducing additives to Glucose 10% solution aseptic technique must be used.

Mix the solution thoroughly when additives have been introduced.

7. APPLICANT/MANUFACTURER

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