Module 1	ADMINISTRATIVE INFORMATION
1.3	Product Information
1.3.1	Summary Product Characteristics (SPC)

Summary Product Characteristics (SPC)

1. Name of the medicinal product

1.1 (Invented) name of the medicinal product

10% Dextrose Water Intravenous Infusion BP 0.9g/100 ml

1.2 Strength

Dextrose 10g/100 ml

1.3 Pharmaceutical form

Infusion.

2. Qualitative and quantitative composition

Each 100 ml contains:

Dextrose Monohydrate BP……10 g

Water for injection BP…Q.S to 100 ml

3. Pharmaceutical form

Intravenous Infusion

4. Clinical particulars

4.1 Therapeutic indications

10% Dextrose Injection, USP is a sterile, no pyrogenic, hypertonic solution of dextrose in water for injection for intravenous injection as a fluid and nutrient replenisher. Each mL of fluid contains 0.5 g dextrose, hydrous which delivers 3.4 kcal/gram. The solution has an osmolarity of 2.53 mOsmol/mL (calc.), a pH of 4.2 (3.5 to 6.5) and may contain sodium hydroxide and/or hydrochloric acid for pH adjustment. The solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only for use as a single-dose injection. When smaller doses are required, the unused portion should be discarded with the entire unit.

4.2 Posology and method of administration

Method of administration: This product is an intravenous Injection.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 30°C does not adversely affect the product.

5% DEXTROSE WATER INTRAVENOUS INFUSION BP		
Module 1	**ADMINISTRATIVE INFORMATION**	CONTD… .
1.3	**Product Information**	
1.3.1	**Summary Product Characteristics (SPC)**	

Posology:

When administered intravenously this solution restores blood glucose levels in hypoglycemia and provides a source of carbohydrate calories. Carbohydrate in the form of dextrose may aid in minimizing liver glycogen depletion and exerts a protein-sparing action. Dextrose injection undergoes oxidation to carbon dioxide and water. Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production). Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na+) plays a major role in maintaining physiologic equilibrium..

4.3 Contraindications

A concentrated dextrose solution should not be used when intracranial or intraspinal hemorrhage is present, nor in the presence of delirium tremens if the patient is already dehydrated. Dextrose injection without electrolytes should not be administered simultaneously with blood through the same infusion set because of the possibility that pseudoagglutination of red cells may occur.

4.4 Special warnings and precautions for use

Pregnancy

Intravenous glucose (dextrose) should be given to a pregnant woman only if clearly needed, and doses should be individualized to the patient's needs to meet fluid and nutritional requirements. Frequent monitoring of serum glucose concentrations is required. Animal reproduction studies have not been conducted; it is not known whether dextrose can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. However, when used appropriately, there appears to be low risk to the clinical use of dextrose products during pregnancy when necessary. Oral glucose supplement products have not been assigned a pregnancy category by the FDA, but are not harmful when used as directed in the

recommended doses to treat episodes of hypoglycemia in the conscious pregnant individual as per guideline recommendations. Glucose (15 grams to 20 grams) is the preferred treatment, although any form of carbohydrate that contains glucose may be used.

Breast-feeding

Glucose and dextrose administration pose no particular risks during breast-feeding. Lactose is the major carbohydrate of human milk and is also the major osmotic constituent of human milk. Synthesis of lactose is the major determinant of the volume of milk produced by the lactating human mammary gland. Lactose is synthesized from free glucose and UDP-galactose. Thus, proper carbohydrate consumption by the mother during lactation is essential to milk production.

Corn hypersensitivity

Use dextrose parenteral solutions with caution in patients with severe corn hypersensitivity. Some intravenous solution manufacturers caution that the dextrose in the solutions can be derived from corn.

Dehydration, intracranial bleeding

A concentrated dextrose solution should not be used when intraspinal or intracranial bleeding is present nor in the presence of delirium tremens if dehydration is present.

Electrolyte imbalance, heart failure, pulmonary edema

Electrolyte imbalance, particularly in serum potassium and phosphate, may occur during prolonged use of concentrated dextrose solutions. The intravenous administration of dextrose solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states (congestive heart failure) or pulmonary edema. Monitor electrolytes; fluid and electrolyte imbalances should be corrected. Essential vitamins and minerals also should be provided as needed.

Extravasation, intramuscular administration, subcutaneous administration

Do not give parenteral dextrose via subcutaneous administration or intramuscular administration. Administer dextrose intravenously, taking care to insure that the needle (or catheter) is well within the lumen of the vein and that extravasation does not occur.

Hyperosmolar hyperglycemic state (HHS), uremia

Administer concentrated dextrose in water intravenous solutions only after suitable dilution. Hypertonic parenteral dextrose solutions should be given slowly. Significant hyperglycemia and possible hyperosmolar hyperglycemic state (HHS) may result from too rapid administration. The physician should be aware of the symptoms of hyperosmolar syndrome, such as mental confusion and loss of consciousness, especially in patients with chronic uremia and those with known carbohydrate intolerance.

Neonates, premature neonates, renal impairment

Use caution when administering intravenous dextrose solutions to patients with renal impairment and particularly neonates, low birth weight infants, and premature neonates since dextrose solution contains aluminum, which may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration in patients with renal impairment. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with renal impairment, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration. In addition, caution should be exercised with low birth weight premature neonates, who are receiving dextrose concentrations of 10% or greater, as they are most susceptible to glucose intolerance and hyperglycemia. Frequent monitoring of serum glucose concentrations is required. In at risk infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible intracerebral hemorrhage.

Diabetes mellitus, hyperglycemia

Intravenous solutions containing dextrose should be used with caution in patients with known hyperglycemia or subclinical or overt diabetes mellitus. Patients may require insulin or other measures to maintain desired serum glucose concentration.

5. Pharmacological properties

5.1 Indication

Drug-drug. Additives: May be incompatible. Must be introduced aseptically, mixed thoroughly, and not stored.

Blood: May cause pseudoagglutination of RBCs. Don't give with blood through same infusion set.

Corticosteroids, corticotropin: May cause increased serum glucose levels. Administer cautiously; monitor patient closely.

Insulin, oral hypoglycemics: May alter drug requirements and cause vitamin B complex deficiency. Monitor serum glucose levels.

Pharmacodynamics

Metabolic action: Dextrose is a rapidly metabolized source of calories and fluids in patients with inadequate oral intake. While increasing blood glucose levels, dextrose may decrease body protein and nitrogen losses, promote glycogen deposition, and decrease or prevent ketosis if sufficient doses are given. Dextrose also may induce diuresis. Parenterally injected doses of dextrose undergo oxidation to carbon dioxide and water. A 5% solution is isotonic and is administered peripherally. Concentrated dextrose infusions provide increased caloric intake with less fluid volume; they may be irritating if given by peripheral infusion. Solutions above 10% should be given only by central venous catheter.

Mechanism of action

Dextrose — major electrolytes of the fluid compartment outside of cells (i.e., extracellular) — work together to control extracellular volume and blood pressure.

Disturbances in sodium concentrations in the extracellular fluid are associated with disorders of water balance.

Absorption/Distribution

As a source of calories and water for hydration, dextrose solutions expand plasma volume.

Metabolism

Metabolized to carbon dioxide and water.

Route of elimination

Substantially excreted by the kidneys. (drugs.com)

In some patients, dextrose solutions may produce diuresis.

Half life

15 minutes.

Clearance

Not Available

Toxicity

The rare inadvertent intravascular administration or rapid intravascular absorption of hypertonic sodium chloride can cause a shift of tissue fluids into the vascular bed, resulting in hypervolemia, electrolyte disturbances, circulatory failure, pulmonary embolism, or augmented hypertension. (toxnet)

Pharmacotherapeutic group: "Electrolytes with Carbohydrates".

Glucose is the principal source of energy in cellular metabolism.

6. Pharmaceutical particulars

6.1 List of excipients

Dextrose Monohydrate BP, Water for Injection .

6.2 Incompatibilities

Do not use equipment containing aluminum (e.g., needles, cannulae) that would come in contact with the drug solution as precipitates may form.

6.3 Shelf life

3 Years

6.4 Special precautions for storage

Keep Pouches in the outer carton in order to protect from light.

6.5 Nature and contents of container

The Pouches are composed of polyolefin/polyamide co-extruded plastic (PL 2442) known as Viaflo. The Pouches were Plugged with stoppers and overwrapped with a protective nylons composed of polyamide/polypropylene, which serves only to provide physical protection to the Pouches. The pouch size is 500 /1000 mL.

6.6 Special precautions for disposal

Use only if the solution is clear, without visible particles and if the container is undamaged.
Administer immediately following the insertion of infusion set.
Do not remove unit from over pouch until ready for use.
The inner bag maintains the sterility of the product.
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.
The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.
Using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of Pyrogens. In the case of adverse reaction, infusion must be stopped immediately.
Additives:
Additives known or determined to be incompatible should not be used.
Before adding a substance or medication, verify that it is soluble and stable, and that the pH range is appropriate. Additives may be incompatible. When introducing additives, the instructions for use of the medication to be added and other relevant literature must be consulted. Mix the solution thoroughly when additives have been introduced. After addition, if there is a color change and/or the appearance of precipitates, insoluble complexes or crystals, do not use. Do not store solutions containing additives. The product should be used immediately after opening. Discard after single use.
Discard any unused portion.

Do not reconnect partially used Pouches.

1. Opening

a. Remove the Nyloning seal from the pouch just before use.

b. Check for minute leaks by squeezing the pouch firmly. If leaks are found, discard solution, as sterility may be impaired.

c. Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.

2. Preparation for administration

Use sterile material for preparation and administration.

a. Suspend container from eyelet support.

b. Remove plastic protector from outlet port at bottom of container:

- grip the small wing on the neck of the port with one hand,
- grip the large wing on the cap with the other hand and twist,
- the cap will pop off

c. Use an aseptic method to set up the infusion

7. Registrant

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