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

4.3% Dextrose Saline Intravenous Infusion BP

1.2 Strength

Sodium chloride 0.18g/100 ml

Dextrose 4.3g/100 ml

1.3 Pharmaceutical form

Infusion.

2. Qualitative and quantitative composition

Each 100 ml contains:

Sodium Chloride BP…....0.18 g

Dextrose Monohydrate BP……4.3 g

Water for injection BP…Q.S to 100 ml

3. Pharmaceutical form

Intravenous Infusion

4. Clinical particulars

4.1 Therapeutic indications

This medication is an intravenous (IV) solution used to supply water, calories, and electrolytes (e.g., sodium, chloride) to the body. It is also used as a mixing solution (diluent) for other IV medications..

5% Dextrose in 0.9% Saline has being used as a blood volume Expander and treatment of Dehydration

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.

Posology:

Dextrose and Sodium Chloride Injection, BP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Dextrose injections with low electrolyte concentrations should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The container label for these injections bears the statement: Do not administer simultaneously with blood.

The intravenous administration of Dextrose and Sodium Chloride Injection, USP (dextrose and sodium chloride inj) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

Excessive administration of Dextrose and Sodium Chloride Injection, USP (dextrose and sodium chloride inj) may result in significant hypokalemia.

In patients with diminished renal function, administration of Dextrose and Sodium Chloride Injection, BP (dextrose and sodium chloride inj) may result in sodium retention.

4.3 Contraindications

Not known to be contra-indicated to any drug.

4.4 Special warnings and precautions for use

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

Caution must be exercised in the administration of Dextrose and Sodium Chloride Injection, BP (dextrose and sodium chloride inj) to patients receiving corticosteroids or corticotropin

Dextrose and Sodium Chloride Injection, USP (dextrose and sodium chloride inj) should be used with caution in patients with overt or subclinical diabetes mellitus.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Dextrose and Sodium Chloride Injection, USP. It is also not known whether Dextrose and Sodium Chloride Injection, USP (dextrose and sodium chloride inj) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness of Dextrose and Sodium Chloride Injection, BP (dextrose and sodium chloride inj) in pediatric patients have not been established by adequate and well controlled trials, however, the use of dextrose and sodium chloride solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population. In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Dextrose and Sodium Chloride Injection, BP (dextrose and sodium chloride inj) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose and Sodium Chloride Injection, BP (dextrose and sodium chloride inj) is administered to a nursing mother.

Geriatric Use

Clinical studies of Dextrose and Sodium Chloride Injection, BP (dextrose and sodium chloride inj) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in

responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency

of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Do not administer unless solution is clear and Stopper Plugging is intact.

4.5 Interaction with other medicinal products and other forms of interaction

Tell your doctor of all prescription and nonprescription medication you may use, especially of: water pills (e.g., furosemide, hydrochlorothiazide), corticotropin (adrenocorticotropic hormone), corticosteroids (e.g., hydrocortisone, prednisone). Do not start or stop any medicine without doctor or pharmacist approval.

4.6 Pregnancy and lactation

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Dextrose and Sodium Chloride Injection, USP. It is also not known whether Dextrose and Sodium Chloride Injection, USP (dextrose and sodium chloride inj) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

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5. Pharmacological properties

5.1 Indication

This intravenous solution is indicated for use in adults and pediatric patients as a source of electrolytes and water for hydration. Also, designed for use as a diluent and delivery system for intermittent intravenous administration of compatible drug additives.

Associated Conditions

- Corneal Edema
- Dehydration
- Hyponatremias
- Nasal irritation
- Skin Irritation
- Hypochloremic state

Associated Therapies

- Wound irrigation therapy
- Parenteral drug administration

Pharmacodynamics

Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid. Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

Mechanism of action

Sodium and chloride — 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

Absorption of sodium in the small intestine plays an important role in the absorption of chloride, amino acids, glucose, and water. Chloride, in the form of hydrochloric

acid (HCl), is also an important component of gastric juice, which aids the digestion and absorption of many nutrients.

Volume of distribution

The volume of distribution is 0.64 L/kg.

Protein binding

Sodium is not bound by plasma proteins.

Metabolism

The salt that is taken in to gastro intestinal tract remains for the most part unabsorbed as the liquid contents pass through the stomach and small bowel. On reaching the colon this salt, together with the water is taken in to the blood. As excesses are absorbed the kidney is constantly excreting sodium chloride, so that the chloride level in the blood and tissues remains fairly constant.Further more, if the chloride intake ceases, the kidney ceases to excrete chlorides. Body maintains an equilibrium retaining the 300gm of salt dissolved in the blood and fluid elements of the tissue dissociated into sodium ions and chloride ions.

Route of elimination

Substantially excreted by the kidneys. (drugs.com)

Half life

17 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"

Sodium Chloride 0.18% and Glucose 4% is an hypotonic solution of sodium chloride and glucose.

The pharmacodynamic properties of this solution are those of its components (glucose, sodium and chloride).

Ions, such as sodium, circulate through the cell membrane, using various mechanisms of transport, among which is the sodium pump (Na-K-ATPase). Sodium plays an important role in neurotransmission and cardiac electrophysiology, and also in its renal metabolism.

Chloride is mainly an extracellular anion. Intracellular chloride is in high concentration in red blood cells and gastric mucosa. Reabsorption of chloride follows reabsorption of sodium.

Glucose is the principal source of energy in cellular metabolism.

6. Pharmaceutical particulars

6.1 List of excipients

Dextrose Monohydrate BP,Sodium Chloride BP, Water for Injections .

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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8. Date of revision of the text –