DESCRIPTION

5% Dextrose and 0.45% Sodium Chloride Injection, USP is a solution of dextrose (5%) and sodium chloride (0.45%) in water for injection intended for intravenous administration. Each milliliter of the 5% Dextrose and 0.45% Sodium Chloride Injection, USP contains dextrose, hydrous 5.0 g and sodium chloride 0.45 g in water for injection. The equivalent of 0.45 mEq of chloride (Cl–) is present in 1 mL of solution. Each milliliter of the solution contains 23 mEq of sodium (Na+) and 15 mEq of chloride (Cl–). The osmolarity is 290 mOsmol/L (calc.). Dextrose, USP is chemically designated C6H12O6 (D-glucose monohydrate) and is a hexose sugar freely soluble in water. It has the following structural formula:

\[ \text{C}_6\text{H}_{12}\text{O}_6 \]

Water balance is maintained by various regulatory mechanisms. Each day the body requires a fluid intake in excess of that excreted in the urine, feces, and respirations to maintain fluid and electrolyte balance. The total daily requirements range from two to three liters (1.0 to 1.5 liters for very low birth weight infants) for maintenance of fluid and electrolyte balance. Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of sodium (Na+) and chloride (Cl–) ions. The intracellular and extracellular fluids contain approximately 150 mEq/L sodium and 10 mEq/L chloride ions, which is hypertonic. The intracellular water is 15 L/kg.

5% Dextrose and 0.45% Sodium Chloride Injection, USP contains no bacteriostatic, antiseptic or added buffer and is intended only as a single-dose injection. When smaller doses are required, the unused portion should be discarded.

INDICATIONS AND USAGE

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirements range from 2 to 3 liters (1.0 to 1.5 liters for very low birth weight infants) for maintenance of fluid and electrolyte balance. Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of sodium (Na+) and chloride (Cl–) ions. The intracellular and extracellular fluids contain approximately 150 mEq/L sodium and 10 mEq/L chloride ions, which is hypertonic. The intracellular water is 15 L/kg.

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CONTRAINDICATIONS

Know none.

WARNINGS

Solutions containing sodium ions should be used with great care, if at all, in patients with congestive heart failure, serum sodium or chloride deficiencies or extracellular fluid volume overload. Sodium retention may occur in patients receiving corticosteroids or corticotropin. The intravenous administration of these solutions can cause fluid overload if the rate of administration is too rapid, if large volumes are administered, or if extravasation is allowed to occur. When administered intravenously, these solutions provide a source of electrolytes that are essential to the maintenance of the fluid and electrolyte homeostasis of the body. The flexibility of administration is a function of the patient’s clinical condition. The fluid and electrolyte requirements of a patient undergoing major surgery may be best met by administration of crystalloids or colloids. The close supervision of laboratory determinations is 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. Solutions containing dextrose should be used with caution in patients with known subclinical or overt diabetes mellitus. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants. In very low birth weight infants, excessive or rapid administration of water and solute may lead to increased serum osmolality and possible intracellular hemolysis.

DOSAGE AND ADMINISTRATION

The dose is dependent upon the age, weight and clinical condition of the patient. As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia. Teratogenic effects

Animal reproduction studies have not been conducted with dextrose or sodium chloride. It is also not known whether dextrose or sodium chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose or sodium chloride should be given to a pregnant woman only if clearly needed.

Pediatric Use

The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants, the volume of fluid may affect fluid and electrolyte balance.

WARNINGS

Solutions containing sodium ions should be used with great care, if at all, in patients with congestive heart failure, serum sodium or chloride deficiencies or extracellular fluid volume overload. Sodium retention may occur in patients receiving corticosteroids or corticotropin. The risk of dilutional states is inversely proportional to the concentration of sodium ions in the solution. In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention. The risk of extracellular fluid overload and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

DRUG INTERACTIONS

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. Solutions containing dextrose should be used with caution in patients with known subclinical or overt diabetes mellitus. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants. In very low birth weight infants, excessive or rapid administration of water and solute may lead to increased serum osmolality and possible intracellular hemolysis.

OVERDOSAGE

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Excessive administration of potassium-free solutions may result in significant hyperkalemia. In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention. The risk of extracellular fluid overload and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

PREGNANCY

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