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Sign & Date					
Art work Description :	GLUCOSE INTRAVENOUS INFUSION BP (5% WV), (10% WV) Insert For Global				
Type of packing material	Meplitho Paper				
GSM of packing material	54 GSM ± 10%				
Dimension of packing material in mm	L: 200 ± 2mm x W: 130 ± 2mm (Folding Size: L: 50 ± 2mm x W: 65 ± 2mm)				
Colour / Pantone Shade for Printing	Black & Screen For the Black				
Reason For Change in A.W./Initiation	New Artwork				
Effective Date					

FRONT

BACK

For the Use of a registered medical practitioner or a Hospital or a laboratory only

GLUCOSE INTRAVENOUS INFUSION BP (5% W/V), (10% W/V)

DESCRIPTION

Glucose Infusion solutions are sterile and nonpyrogenic. They are parenteral solutions containing 5% and 10% concentrations of glucose in water for injection intended for intravenous administration. The solutions contain no bacteriostat, antimicrobial agent or added buffer and each is intended only as a single-dose injection. When smaller doses are required the unused portion should be discarded. The solutions are parenteral fluid and nutrient replenishers. Glucose, is chemically designated D-glucose monohydrate (C₆H₁₂O₆ · H₂O), a hexose sugar freely soluble in water.

COMPOSITION

	Glucose (5% w/v)	Glucose (10% w/v)
Each 100 mL contains		
Glucose [as anhydrous] BP	5.0 gm	10.0 gm
Water for Injections BP	q. s.	q. s.

CLINICAL PHARMACOLOGY

When administered intravenously, these solutions provide a source of water and carbohydrate. Isotonic and hypertonic concentrations of glucose are suitable for parenteral maintenance of water requirements when salt is not needed or should be avoided.

Solutions containing carbohydrate in the form of glucose restore blood glucose levels and provide calories. Carbohydrate in the form of glucose may aid in minimizing liver glycogen depletion and exerts a protein-sparing action. Glucose injected parenterally 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 daily requirements range 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.

INDICATIONS AND USAGE

Intravenous solutions containing glucose are indicated for parenteral replenishment of fluid and minimal carbohydrate calories as required by the clinical condition of the patient.

CONTRAINDICATIONS

Glucose 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.

WARNINGS

Excessive administration of potassium-free solutions may result in significant hypokalemia. The intravenous administration of these solutions can cause fluid and/or solute overload 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 administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

PRECAUTIONS

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 glucose should be used with caution in patients with known subclinical or overt diabetes mellitus. Do not administer unless solution is clear and container is undamaged. Discard unused portion.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies with Glucose Infusion have not been

performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy: Teratogenic effects

Pregnancy Category C. Animal reproduction studies have not been conducted with glucose. It is also not known whether glucose can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Glucose should be given to a pregnant woman only if clearly needed.

Nursing Mothers:

Caution should be exercised when Glucose Infusion is administered to a nursing mother. 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. Frequent monitoring of serum glucose concentrations is required when glucose is prescribed to pediatric patients, particularly neonates and low birth weight infants. In very low birth weight infants, excessive or rapid administration of glucose injection may result in increased serum osmolarity and possible intracerebral hemorrhage.

Geriatric Use: An evaluation of current literature revealed no clinical experience identifying differences in response between 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.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures.

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 glucose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

DRUG INTERACTIONS

Additives may be incompatible. When introducing additives, use aseptic technique, mix thoroughly and do not store. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

STORAGE

Store below 30° C.

PRESENTATION

100 mL, 250 mL, 350 mL, 500 mL, 540 mL & 1000 mL plastic bottle.

REFERENCES

Martindale - The Complete Drug Reference Book, Thirty fourth edition, Edited by Sean C Sweetman.

aculife®

Manufactured in India by:
Aculife Healthcare Pvt. Ltd.
Sachana, Gujarat 382150, India.

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