Pack Insert

210mm

AXADEX D5
Glucose Intravenous Infusion BP 5%w/v

1.Composition
Each ml contains:
Glucose Anhydrous BP……..0.5%w/v
Water for injections BP……..……q.s

2.Dosage form
Solution for infusion.
Clear solution, free from visible particles.
Osmolarity : 278 mOsm/l.(approx.)
pH : 3.5 – 6.5

3.Indications and Usage
Glucose Intravenous Infusion BP 5% w/v is indicated for the treatment of carbohydrate and fluid depletion.
Glucose Intravenous Infusion BP 5%w/v is also used as a vehicle and diluent for compatible medicinal products for parenteral administration.

4.Clinical Pharmacology:
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 Intravenous Infusion BP 5% w/v
is given as a source of carbohydrate in parenteral nutrition. The Glucose Intravenous Infusion BP 5%w/v provides a caloric intake of 200 kcal/l. Furthermore, this glucose solution for infusion allows hydric supplementation without ionic supplementation.
Glucose Intravenous Infusion BP 5% w/v 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.
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.Dosage and Administration
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 / 24
- > 20 kg body weight:	1500 ml + 20 ml / kg over 20 kg / 2

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 Glucose Intravenous Infusion BP 5%w/v 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.
Glucose Intravenous Infusion BP 5%w/v is a isosmotic 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.

6.Contraindication: 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

7.Warnings and Precautions
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,
- 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.
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.
Glucose Intravenous Infusion BP 5%w/v 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),
- 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. Solutions containing glucose should therefore be used with caution, if at all, in patients with known allergy to corn or corn products.
The infusion must be stopped immediately if any signs or symptoms of a

160mm