1.4 Product information

1.4.1 Summary of Product Characteristics

Product name

Product brand name: 5% Glucose Injection

International Nonproprietary name: 5% Glucose Injection

Qualitative and quantitative composition

Each bottle of 5% Glucose Injection contains anhydrous glucose 25g, Water for injection 500ml q.s.

Pharmaceutical form

Large volume injection, a colorless solution.

Clinical data

Therapeutic indications

5% Glucose Injection is indicated for the treatment of carbohydrate and fluid depletion.

5% Glucose Injection is also used as a vehicle and diluent for compatible medicinal products for parenteral administration.

Dosage and method of 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: 100ml/kg/24h.

10-20kg body weight: 1000ml+50ml/kg over 10kg/24h

＞20kg body weight: 1500ml+20ml/kg over 20kg/24h

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 5% Glucose Injection 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.

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.

5% Glucose Injection intravenous infusion is a isosmotic solution. Please see section 3 for the information about the osmolarity of the 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 needs 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.

Contraindications

(1) Diabetes ketosis acidose;

(2) Hyperglycemia non-ketosis hyperosmotic state;

Special warnings and precautions for use

(1) High dose dextrose during parturition may stimulate the secretion of insulin for

the fetus, which can lead to glycopenia.

(2) The product should be administered cautiously in the following cases: i. Tolerance test of oral dextrose for the patients whose stomach has been cut partially may lead to dumping syndrome and hypoglycemia. ii. The patients with periodic paralysis or hypopotassemia; iii. Stress condition or glucocorticoid administration may lead to hyperglycemia; iv. When the product is administered for the patients with dropsy, cardiac and kidney insufficiency, and ascites due to cirrhosis, water retention may happen, so the administration dosage should be controlled; the drip speed should be controlled strictly for the patients with cardiac functional insufficiency.

Interaction with other medicinal products and other forms of interaction

Both the glycaemic effects of 5% Glucose Injection and its effects on water and electrolyte balance should be taken into account when using 5% Glucose Injection in patients treated with other substances that affect glycaemic control, or fluid and/or electrolyte balance.

Concomitant administration of catecholamines and steroids decreases the glucose up-take.

Drugs leading to an increased vasopressin effect

The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids.

• Drugs stimulating vasopressin release, e.g.: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics.

• Drugs potentiating vasopressin action, e.g.: Chlorpropamide, NSAIDs, cyclophosphamide

• Vasopressin analogues, e.g.: Desmopressin, oxytocin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.

No interaction studies have been performed.

Pregnancy and breastfeeding

High dose dextrose during parturition may stimulate the secretion of insulin for the fetus, which can lead to glycopenia.

Effects on ability to drive and use machines

None known.

Side effects

(1) Phlebitis may happen when high-concentration glucose injection was administered by drip, but the occurrence rate will decrease when administered to the large vein.

(2) Exosmosis of high-concentration glucose injection may lead to locality gall.

(3) Reactive hypoglycemia: when administered combined with insulin with overdose, reactive hypoglycemia may happen for the patients with original hypoglycemia tendency and when intravenous hyperalimentation treatment was ceased suddenly.

(4) Hyperglycemia non-ketosis coma: It is usually happen when the high-concentration was administered or intravenous hyperalimentation treatment was used for the patients who with the diabetes, stress condition, with the treatment of high-dose glucocorticoid, or for the patients who received peritoneal dialysis for the treatment of toxuria.

(5) Electrolyte disturbance: Glucose is administered singly for long term may lead to hypo-potassium, hypo-sodium, and hypophosphatemia.

(6) Original cardiac functional insufficiency;

(7) Hyperpotassemia, the cases may happen occasionally when the patients with I diabetes is administered with high concentration glucose injection.

Overdose

Prolonged administration or rapid infusion of large volumes of Glucose 5% may cause hyperosmolarity and hyponatraemia, dehydration, hyperglycaemia, hyperglycosuria, osmotic diuresis (due to the hyperglycaemia) and water intoxication and oedema. Severe hyperglycaemia and hyponatraemia may be fatal.

In case of suspected overdose, treatment with 5% Glucose Injection must be stopped immediately. Management of overdose is symptomatic and supportive, with appropriate monitoring.

Pharmacological properties

Glucose is a monosaccharide, which provides a source of energy. Low concentration glucose solutions are suitable diluents for drugs because glucose, as a natural substrate of the cells in the organism, is ubiquitously metabolized. Under physiological conditions glucose is the most important energy-supplying carbohydrate with a caloric value of approx.17 kJ/g or 4 kcal/ g. Glucose utilization disturbances (glucose intolerance) can occur under conditions of pathological metabolism. These mainly include diabetes mellitus and states of metabolic stress (e.g. intra-, and

postoperatively, severe disease, injury), hormonally mediated depression of glucose tolerance, which can even lead to hyperglycaemia without exogenous supply of the substrate. Hyperglycaemia can-depending on its severity-lead to osmotically mediated renal fluid losses with consecutive hypertonic dehydration, to hyperosmotic disorders up to and including hyperosmotic coma. Metabolism of glucose and electrolytes are closely related to each other. Potassium, magnesium and phosphate requirements may increase and may therefore have to be monitored and supplemented according to individual needs. Especially cardiac and neurological functions may be impaired without supplementation.

Pharmaceutical properties

List of excipients

Water for injection

Incompatibilities

Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

Storage durability

Three years.

Special precautions for storage

Store in a tightly closed container

Nature and contents of container

5% Glucose Injection is contained in PP (polypropylene) bottle, each carton contains 25 bottles.

Special precautions for disposal and other handling

Check for leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired.

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.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Marketing Authorization Holder

Shijiazhuang No.4 Pharmaceutical Co., Ltd.

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