Package Insert

DEXTROSE 50%

1. Product name

DEXTROSE 50%

2. Name and strength of active ingredient (s)

Each 10 mL contains: - Dextrose monohydrate 5 g

3. Product description

Clear, colorless to pale yellow sterile solution for injection

4. Pharmacodynamic/Pharmacokinetics

The metabolism of glucose is an energy source for the body. Glucose is rapidly metabolized into carbon dioxide and water.

5. Indication

- Provides a source of calories
- Therapy of hypoglycemia resulting from insulin excess or from other causes.
- Used for temporary relief from the symptoms of cerebral oedema and from hypoglycemic coma.
- Used to reduce increased cerebrospinal pressure and/or oedema due to delirium tremens or acute alcoholic intoxication.
- Hyperosmotic glucose with or without insulin may correct hyperkalemia in renal failure.

6. Recommended Dose

Dosage of glucose depends on the age, weight, clinical condition, the fluid, electrolyte and acid base balance of the patient. For the treatment of hypoglycemia resulting from insulin excess or other causes in adults (including the elderly) and children, the usual dose is as follows:

20-50 ml of Dextrose 50% administered slowly intravenously. This represents 3mls per minute.

Repeated doses and supportive therapy may be required in some cases.

7. Mode of Administration

Intravenous route, should be administered via a central vein after appropriate dilution. When used for the emergency treatment of hypoglycemia, may be administered slowly into a peripheral vein.

8. Contraindication

- Hypersensitivity to the active substance and known allergy to corn or corn products.
- The glucose – galactose malabsorption syndrome.
- Anuria or intraspinal or intracranial hemorrhage, or ischemic stroke and in patients with delirium tremens if such patients are already dehydrated.
- Hyperglycemic coma.

9. Warning and Precaution

Glucose solutions should be used with caution in patients with overt or known sub-clinical diabetes mellitus, carbohydrate intolerance for any reason, severe under-nutrition, thiamine deficiency, hypophosphatemia, hemodilution, sepsis, trauma, shock, metabolic acidosis or severe dehydration.

Prolonged use in parenteral nutrition may affect insulin production; blood and urine glucose should be monitored.

Hyponatremia: Patients with non-osmotic vasopressin release (e.g., in acute illness, pain, post-operative stress, infections, burns, and CNS disease), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists are at risk of acute hyponatremia upon infusion of hypotonic fluids.

Acute hyponatremia can lead to acute hyponatremic encephalopathy (brain oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain oedema are at particular risk of severe, irreversible and life-threatening brain injury.

Children, women in the fertile age and patients with reduced cerebral compliance (e.g., meningitis, intracranial bleeding, and cerebral contusion) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatremia.

Intravenous administration of Dextrose 50% may result in other electrolyte disturbances such as: hypokalemia, hypophosphatemia and hypomagnesemia.

Glucose solutions should not be infused concomitantly through the same IV set as blood because agglomeration or hemolysis may occur.

10. Interactions with Other Medicaments

Parenteral fluids, especially those containing sodium ions, should be administered with caution to patients receiving corticosteroids or corticotropin.

11. Pregnancy and Lactation

Pregnancy

Intravenous glucose may result in fetal insulin production, with an associated risk of rebound hypoglycemia in the neonate. Infusions of glucose administered during Caesarean section and labor should not exceed 5-10g glucose/hour.

Dextrose 50% should be administered with special caution for pregnant women during labor particularly if administered in combination with oxytocin due to the risk of hyponatremia.

Lactation

Glucose/metabolites are excreted in human milk, but at therapeutic doses of Dextrose 50% no effects on the breast-fed newborns/infants are anticipated. Dextrose 50% can be used during breast-feeding as indicated.

12. Undesirable effects

Undesirable effects are listed according to their frequencies as follows:

Very common (≥ 1/10); Common (≥ 1/100 to < 1/10); Uncommon (≥ 1/1,000 to < 1/100); Rare (≥ 1/10,000 to <1/1,000); Very rare (<1/10,000), Not known (cannot be estimated from the available data)

General disorders:

Not known: Local reactions at the site of administration, including local pain, vein irritation, thrombophlebitis or tissue necrosis in case of extravasation.

Metabolism and nutrition disorders:

Not known: Hospital acquired hyponatremia*, hyperglycemia**, hypokalemia, hypophosphatemia, hypomagnesemia, fluid and electrolyte imbalance.

Neurological disorders:

Not known: Hyponatremic encephalopathy

* Hospital acquired hyponatremia may cause irreversible brain injury and death due to development of acute hyponatremic, encephalopathy.

** Hyperglycemia (possibly indicated by mental confusion or loss of consciousness) and glycosuria may occur as a result of the rate of administration or metabolic insufficiency. If undetected and untreated hyperglycemia can lead to dehydration, hyperosmolar coma and death.

13. Overdose and Treatment

Hyperglycemia and glycosuria, if undetected, can lead to mental confusion, dehydration, hyperosmolar coma and death. Appropriate treatment may include decreasing the infusion rate of glucose and administration of insulin.

14. Storage Condition

Store below 30 ºC

15. Dosage Forms and Packaging Available

Plastic type (polypropylene) size 20, 50 and 100 mL with or without paper box of 1, 10, 12, 20, 24, 36, 50 and 60 bottles.

16. Name and Address of Manufacturer/Marketing Authorization Holder

ABLE MEDICAL COMPANY LIMITED

111 Moo. 9 Nong Son, Chiang Yuen, Mahasarakham 44160, Thailand

17. Date of revision of package insert

21 April 2023