SUMMARY OF PRODUCT CHARACTERISTICS

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1. Name of the Medicinal product
DEXTROSE INJECTION USP 40%

2. Quality and Quantitative Composition

Dextrose monohydrate USP 40%w/vWater for injection
USP q.s

3. Pharmaceutical dosage form:
Injection
Clear , Colourless solution .

pH: 3.2 to 6.5

4.Clinical particulars
4.1 Therapeutic indication

DEXTROSE INJECTION USP 40%, 40%, is used in parenteral hyperalimentation. It is a hypertonic solution and, when administered intravenously, cause cellular dehydration. It has been employed to promote diuresis by increasing the osmotic pressure of the glomerular filtrate. Its hypertonic property makes it valuable in the following special clinical uses, which may be summarized as follows:

a) For its concentrated food value in patients in whom more dilute solutions are contraindicated by actual or impending edema, such as exist in surgical as well as nonsurgical patients.
b) 40%: Used in the treatment of insulin hypoglycemia (hyperinsulinemia or insulin shock) to restore blood Dextrose levels.

For reduction of increased cerebrospinal pressure and/ or cerebral edema due to delirium tremens or acute alcoholic intoxication. Increased cerebrospinal fluid pressure may be depressed for two to four hours after intravenous injection of 20 mL of 40% dextrose solution

4.2 Posology and method of administration

Dextrose 40% must be administered by the intravenous route; it must not be administered by subcutaneous or intramuscular route. Except in the emergency treatment of severe hypoglycaemia, Dextrose 50% should be administered via a central vein after appropriatedilution. When used for the emergency treatment of hypoglycaemia, Dextrose 50% may be administered slowly into a peripheral vein at a rate not greater than 3mls per minute.
Dosage of Dextrose depends on the age, weight, clinical condition, the fluid, electrolyte and acid base balance of the patient. For the treatment of hypoglycaemia resulting from insulin excess or other causes in adults (including the elderly) and children, the usual dose is as follows:
20-50ml of Dextrose 50% administered slowly intravenously. This represents 3mls per minute. Repeated doses and supportive therapy may be required in some cases.

Mode of Administration: Intravenous Injection

4.3 Contraindications

Dextrose 40% is contraindicated in patients with the Dextrose - galactose malabsorption syndrome. Hypertonic Dextrose solutions are contraindicated in patients with anuria or intraspinal or intracranial haemorrhage, or ischaemic stroke and in patients with deliriumtremens if such patients are already dehydrated. Hypertonic Dextrose solutions are also contraindicated in patients with diabetic coma or known allergy to corn or corn products.

4.4 Special warnings and precautions for use

Hypertonic solutions of Dextrose should be administered via a large central vein to minimise damage at the site of injection (see section 4.2 Posology).
Dextrose 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, hypophosphataemia, haemodilution, sepsis, trauma, shock, metabolic acidosis or severe dehydration.
Rapid administration of hypertonic Dextrose solutions may produce substantial hyperglycaemia and hyperosmolar syndrome; patients should be observed for signs of mental confusion and loss of consciousness, especially those patients with chronic uraemia or carbohydrate intolerance.
Prolonged use in parenteral nutrition may affect insulin production; blood and urine Dextroseshould be monitored.
Changed in fluid balance, electrolyte concentrations and acid-base balance should be evaluatedduring prolonged therapy. Intravenous administration of Dextrose may result in hypokalaemia,hypophosphataemia and hypomagnesaemia.

4.5 Interaction with other medicinal products and other forms of interactionNone

4.6 Fertility, pregnancy and lactation

Intravenous Dextrose may result in foetal insulin production, with an associated risk of rebound hypoglycaemia in the neonate. Injections of Dextrose administered during Caesarean section and labour should not exceed 5-10g Dextrose/hour.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Metabolic and nutrition disorders:
Hyperglycaemia, hypokalaemia, hypophosphataemia, hypomagnesaemia, fluid and electrolyteimbalance.
Hyperglycaemia (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 hyperglycaemia can lead to dehydration, hyperosmolar coma and death.
The administration of Dextrose without adequate levels of thiamine may precipitate overt deficiency states e.g. Wernicke's encephalopathy. Sodium retention, oedema, pulmonary oedema and congestive heart failure may be induced in patients with severe under-nutrition.
Nervous system:
See Metabolic and nutrition disorders.General
and administration site disorders:
Pain at the injection site, vein irritation, venous thrombosis,phlebitis.Reporting of
suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

Overdose of Dextrose 40% may lead to hyperglycaemia and glycosuria leading to dehydration, hyperosmolar coma and death.
In the event of overdose of Dextrose 40% it may be necessary to administer appropriatedoses ofinsulin.

5.0 Pharmacological properties

5.1 Pharmacodynamic properties:

Not applicable

5.2 Pharmacokinetic properties

Dextrose, the natural sugar occurring in blood, is the principal source of energy for the body. In addition to its importance as the primary source of energy for the body, dextrose has a multitude of other essential roles in the body economy. It is readily converted to fat, which provides a rich store of energy in a concentrated form (9 cal/g). Dextrose is also stored within the liver and muscles as glycogen. When a rapid rise in blood sugar is demanded by the body, glycogen is quickly liberated as D-Dextrose. When the supply of dextrose is insufficient, the body mobilizes its fat stores, which are converted to acetate with production of energy by the same oxidative pathways employed in the combustion of the dextrose.

Another important use of dextrose in the total body economy is the sparing of proteins, which, in the absence of dextrose, may be deaminated to provide carbon moieties from their constituent amino acids. These deaminated fragments may undergo oxidation in order to release energy.

Dextrose is also the probable source of glucuronic acid, with which many foreign substances and their metabolites combine to form excretion products. It probably provides the basic substances required for the formation of hyaluronates and chondroitin sulfates, the supporting structure of the organism. It can be converted to a pentose essential for the formation of nucleic acids by the cells.

5.3 Preclinical safety data

No further information other than that which is included in the Summary of Product Characteristics

6.0 Pharmaceutical particulars

6.1 List of excipients:

Water for injection USP

6.2 Incompatibilities:

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.Unless compatibility with other solutions/drugs has been confirmed, the Injection solution must always be administered separately. The visual signs of incompatibility are e.g. precipitation, clouding, and discoloration.Incompatibility appears with all Injection solutions/drugs that are physically or chemically unstable at the pH of thesolutions (e.g. penicillins, heparin solutions), especially in combination with solutionsadjusted to an alkaline pH (pH of Dextrose anhydrous: 3.2 – 6.5)

6.3 Shelf life: 24 Months

6.4 Special precautions for storage: Store below 30°C protect from light. Do not refrigerate orfreeze.

6.5 Nature and contents of container: 20 ml hermetically FFS sealed translucent packed in polyethylene sealed cover and kept in a carton with a package insert

6.6 Special precautions for disposal and other handling:

None

7.0 Marketing authorisation holder:

Manufacturer:
Global Pharma Healthcare Pvt. Ltd.,
A-9, SIDCO PHARMACEUTICAL Complex, Alathur, -603110,
Tamil Nadu, INDIA

8.0 Marketing authorization number(s):
05294/07174/REN2019

9.0 Date of first authorization /renewal of the authorization:
Approval date: 27-08-2020

10. Date of revision of the text:

July 2024