Summary of Product Characteristics:

1. Name of the finished Pharmaceutical Product

Dextrose Injection USP 50% W/V

2. Qualitative and Quantitative

Composition Qualitative declaration

Dextrose Monohydrate USP

Quantitative declaration

For full list of Excipients, see section 6.1.

3. Pharmaceutical Form

Injection for Parenteral Nutrition A clear colourless solution.

4. Clinical Particulars

4.1 Therapeutic Indications

Dextrose Injection is indicated in the treatment of Insulin Hypoglycemia (Hyperinsulinemia or Insulin Shock) to restore blood glucose levels.

The solution is also indicated, after dilution, for intravenous infusion as a source of carbohydrate calories in patients whose oral intake is restricted or inadequate to maintain Nutritional requirements.

Slow infusion of hypertonic solutions is essential to insure proper utilization of Dextrose and avoid production of Hyperglycemia.

4.2 Posology and Method of Administration

Route and method of administration: For IV Infusion use

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

For peripheral vein: It should be made slowly preferably through a small bore needle into a large vein, to minimize venous irritation. The maximum rate at which dextrose can be infused without producing glycosuria is 0.5 g/kg of body

weight/hour. About 95% of the dextrose is retained when infused at a rate of 0.8 g/kg/hr. In insulin-induced hypoglycemia, (I.V) injection of 10 to 25 grams of dextrose (20 to 50 mL of 50% dextrose) is usually adequate. Repeated doses and supportive treatment may be required in severe cases. A specimen for blood glucose determination should be taken before injecting the dextrose. In such emergencies, dextrose should be administered promptly without awaiting pretreatment test results.

For central vein: Do not infuse concentrated solution rapidly. It should be administered via central vein only after suitable dilution. Never stop infusion abruptly. The maximum rate at which dextrose can be infused without producing glycosuria. Dextrose injection USP for total parenteral nutrition: administered by slow (I.V) intravenous infusion, after admixture with compatible solutions via an indwelling catheter with the tip positioned in a large central vein, preferably the superior vena cava, or after dilution with sterile water for injection. Dosage should be adjusted to meet individual patient requirements. Patients should be necessary to monitor under clinical evaluation and periodic laboratory determinations, changes in fluid balance, electrolyte concentrations and acid-base balance during prolonged therapy or whenever the condition of the patient warrants such evaluation.

Use in Paediatric Patients

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 (see section 4.4).

4.3 Contraindications

It contraindicated in patient with history of hypersensitivity to dextrose monohydrate or other ingredients. It should not be use (concentrated solution) when intracranial or intraspinal hemorrhage is present, nor in the presence of delirium tremens if the patient is already dehydrated. Dextrose 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.

4.4 Special Warnings and Special Precautions for Use

WARNINGS

Not for direct intravenous infusion. Must be appropriately diluted before use. The admixture obtained should be administered through a central or peripheral venous line depending on its final osmolarity.

Unless appropriately diluted infusion of hypertonic glucose solutions into a peripheral vein may result in vein irritation, vein damage, and thrombosis. Strongly hypertonic solutions should only be administered through an indwelling intravenous catheter with the tip located in a large vein such as the superior vena cava.

Prolonged intravenous infusion of this solution may cause thrombophlebitis extending from the site of infusion.

Dilution and other effects on serum electrolytes

Glucose intravenous infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization (see section 4.2).

Depending on the tonicity of the solution, 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:

- hypo- or hyperosmotic hyponatraemia (see below),

- hypokalaemia,

- hypophosphatemia,

- hypomagnesaemia,

- overhydration/hypervolemia 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

Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns, and CNS diseases), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic 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 hyponatraemia.

Hypoosmotic hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, cerebral oedema, and death. Acute symptomatic hyponatraemic encephalopathy is considered a medical emergency.

The risk for developing hypoosmotic hyponatraemia is increased, for example,

• in children

• in elderly patients

• in women

• postoperatively

• in persons with psychogenic polydipsia

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 (see below).

Hyperglycaemia

As with the intravenous administration of nutrients (e.g., glucose, amino acids and lipids) in general, metabolic complications may occur if the nutrient intake is not adapted to the patient's requirements, or the metabolic capacity of any given dietary component is not accurately assessed. Adverse metabolic effects may arise from administration of inadequate or excessive nutrients or from inappropriate composition of an admixture for a particular patient's needs.

Rapid administration of glucose solutions may produce substantial hyperglycaemia and a hyperosmolar syndrome.

To reduce the risk of hyperglycaemia-associated complications, the infusion rate must be adjusted and/or insulin administered.

Intravenous glucose should be administered with caution in patients with, for example:

- impaired glucose tolerance (such as in patients with renal failure or diabetes mellitus, 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 metabolisation of pyruvate),

- water and electrolyte disturbances that could be aggravated by increased glucose and/or free water load (see above).

- 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 (see below).

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 (see section 4.8).

Solutions containing glucose should 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 suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Refeeding syndrome

Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intakes while avoiding overfeeding can prevent these complications.

Liver disorders

Hepatobiliary disorders including cholestasis, hepatic steatosis, fibrosis and cirrhosis, possibly leading to hepatic failure, as well as cholecystitis and cholelithiasis are known to develop in some patients on parenteral nutrition. The etiology of these disorders is thought to be multifactorial and may differ between patients. Patients developing abnormal laboratory parameters or other signs of hepatobiliary disorders should be assessed early by a clinician knowledgeable in liver diseases in order to identify possible causative and contributory factors, and possible therapeutic and prophylactic interventions.

Catheter infection and sepsis

Infection and sepsis may occur as a result of the use of intravenous catheters to administer parenteral formulations, poor maintenance of catheters or contaminated solutions.

Immunosuppression and other factors such as hyperglycaemia, malnutrition and/or their underlying disease state may predispose patients to infectious complications.

Careful symptomatic and laboratory monitoring for fever/chills, leukocytosis, technical complications with the access device, and hyperglycaemia can help recognize early infections.

The occurrence of septic complications can be decreased with heightened emphasis on aseptic technique in catheter placement, maintenance, as well as aseptic technique in nutritional formula preparation.

Precipitates

Pulmonary vascular precipitates have been reported in patients receiving parenteral nutrition. In some cases, fatal outcomes have occurred. Excessive addition of calcium and phosphate increases the risk of the formation of calcium phosphate precipitates. Precipitates have been reported even in the absence of phosphate salt in the solution.

In addition to inspection of the solution, the infusion set and catheter should also periodically be checked for precipitates.

If signs of pulmonary distress occur, the infusion should be stopped and medical evaluation initiated.

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 a consulting physician experienced in paediatric intravenous fluid therapy.

In order to avoid potentially fatal over infusion of intravenous fluids to the neonate, special attention needs to be paid to the method of administration. When using a syringe pump to administer intravenous fluids or medicines to neonates, a bag of fluid should not be left connected to the syringe.

When using an infusion pump all clamps on the intravenous administration set must be closed before removing the administration set from the pump, or switching the pump off. This is required regardless of whether the administration set has an anti-free flow device.

The intravenous infusion device and administration equipment must be frequently monitored.

Paediatric glycaemia related issues

Newborns, especially those born premature and with low birth weight - are at increased risk of developing hypo- or hyperglycaemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycaemic control in order to avoid potential long term adverse effects.

Hypoglycaemia in the newborn can cause prolonged seizures, coma and brain damage. Hyperglycaemia has been associated with intraventricular haemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitits, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

Paediatric hyponatraemia-related issues

Children (including neonates and older children) are at increased risk of developing hypoosmotic hyponatraemia as well as for developing hyponatraemic encephalopathy.

Plasma electrolyte concentrations should be closely monitored in the paediatric population.

Rapid correction of hypoosmotic hyponatraemia is potentially dangerous (risk of serious neurologic complications). Dosage, rate, and duration of administration should be determined by a physician experienced in paediatric intravenous fluid therapy.

Geriatric Use

When selecting the type of infusion solution and the volume/rate of infusion for a geriatric patient, consider that geriatric patients are generally more likely to have cardiac, renal, hepatic impairment, and other diseases or concomitant drug therapy.

Blood

Glucose solution (an aqueous, i.e., electrolyte-free glucose solution) should not be administered through the same equipment as whole blood, as haemolysis and pseudoagglutination can occur.

4.5 Interaction with other FPPs and other Forms of interaction

It may interact with corticosteroids, Corticotropin (increased risk of fluid) and electrolyte, glucose (increased level).

4.6 Pregnancy and Lactation

Intrapartum maternal intravenous glucose infusion may result in foetal insulin production, with an associated risk of foetal hyperglycaemia and metabolic acidosis as well as rebound hypoglycaemia in the neonate.

Pregnancy: It is also not known whether dextrose can cause fetal harm when administered to a Pregnant woman or can affect reproduction capacity. Dextrose should be given to a pregnant woman only if clearly needed.

Fertility

There are no adequate data of the effect of Glucose on fertility.

Lactation: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when 50% Dextrose Injection USP is administered to a nursing mother.

4.7 Effects on ability to Drive and use Machines

Patients should be cautioned about engaging in activities requiring mental alertness for a few hours after the drug has been administered.

4.8 Undesirable Effects

Hyperosmolar syndrome, Confusion, loss of consciousness, febrile response, infection at the site of injection, thrombosis or phlebitis, hypervolemia. If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic counter measures and save the remainder of the fluid for examination if deemed necessary.

The following adverse reactions have been reported in the post-marketing experience, listed by MedDRA System Organ Class (SOC), then, where feasible, by Preferred Term in order of severity.

System Organ Class	*Adverse reaction (MedDRA term)*	*Frequency**
Immune system disorders	Anaphylactic reaction**	Not known
	Hypersensitivity**	Not known
Metabolism and nutrition disorders	Hyperglycaemia	Not known
	Hospital Acquired Hyponatraemia***	Not known
Skin and subcutaneous tissue disorders	Rash	Not known
Nervous system disorders	Hyponatraemic encephalopathy***	Not known
General disorders and administration site conditions	Chills	Not known
	Pyrexia	Not known
	Infection at site of injection	Not known
	Thrombophlebitis	Not known
	Infusion site reactions including,	Not known

	• Infusion site phlebitis • Infusion site erythema	

* Cannot be estimated from the available data

** Potential manifestation in patients with allergy to corn, see section 4.4.

*** Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2 and 4.4).

Other adverse reactions reported with glucose injection/infusions include:

• Infusion site thrombophlebitis (associated with hyperosmolar solutions)

• Adverse reactions reported when glucose is used with parenteral nutrition:

- Hepatic failure, Hepatic cirrhosis, Hepatic fibrosis, Cholestasis, Hepatic steatosis, Blood bilirubin increased, Hepatic enzyme increased, Cholecystitis, Cholelithiasis

- Pulmonary vascular precipitates

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org .

4.9 Overdose

In event of overdose during therapy of may lead to hyperglycaemia and glycosuria leading to dehydration, hyperosmolar, the treatment should be re-evaluating the patient and introduce appropriate corrective measures to administer appropriate doses of insulin.

Prolonged administration or rapid infusion of large volumes of the product may cause hyperosmolarity and hyponatraemia, dehydration, hyperglycaemia, hyperglucosuria, osmotic diuresis (due to hyperglycaemia) and water intoxication and oedema. Severe hyperglycaemia and hyponatraemia may be fatal (see sections 4.4 and 4.8).

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

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Pharmacotherapeutic Group: Injection for parenteral nutrition, carbohydrates.

Prevents Protein and Nitrogen Loss, promotes glycogen deposition and ketone accumulation (through osmotic diuretic action). The metabolism of glucose is an energy source for the body.

5.2 Pharmacokinetic Properties

After (I.V) administration, restores blood glucose levels in hypoglycemia and provides a source of carbohydrate calories. Carbohydrate in the form of dextrose may aid in minimizing liver glycogen depletion and exerts a protein sparing action. Dextrose undergoes oxidation to carbon dioxide and water and rapidly metabolized. Water is an essential constituent of all body tissues and approx. seventy percent of total body weight. Average normal essential ranges 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.

5.3 Preclinical Safety data

There is limited information on nonclinical toxicology regarding Dextrose Injection USP 50%w/v.

6. Pharmaceutical Particulars

6.1 List of Excipients

Hydrochloric Acid BP

Sodium Hydroxide BP

Water for Injections BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 Months.

6.4 Special Precautions For Storage

Do not Store above 30°C. Protect from Light.

6.5 Nature and Contents of Container

A clear Colourless solution filled in 50 ml clear Glass USP TYPE-I Bottle with 32 mm Grey bromobutyl Unistar RFU Sterile rubber Stopper having 32 mm Yellow colour Flip off seal is packed in the printed carton with packing insert.

6.6 Instructions for use and handling and disposal

Dilution or addition to parenteral nutrition admixtures must take place in controlled and validated aseptic conditions.

The product should be inspected visually for particulate matter and discoloration after admixing and prior to administration. Do not administer unless the solution is clear and the seal is intact.

Check compatibility with other admixture components before use.

Additives known or determined to be incompatible with glucose as a diluent should not be used. The instructions for use of the medication to be added, including information on storage, must be consulted.

Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of the glucose solution is appropriate.

Mix the solution thoroughly when additives have been introduced.

Use of an in-line filter is recommended during administration of all parenteral solutions where possible.

Single use only.

Do not store partially used bags.

Discard any unused portion, waste materials and all associated devices.

Risk of Air Embolism

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

7.1 Name and Address of Manufacturer

LINCOLN PHARMACEUTICALS

LIMITED

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8. Registration Number

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10. Date of Publication of This Package Insert

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11. Date of Revision of text

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12. Dosimetry (If Applicable)

Not Applicable

13. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable