Approved Professional Information for

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS

SCHEDULING STATUS S3

1. NAME OF THE MEDICINE

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 20 ml contains 10 g of dextrose anhydrous.

Excipient with known effect:

Contains sugar (dextrose).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless to straw-coloured solution for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Acute management of hypoglycaemia or insulin-induced hypoglycaemic coma.

4.2 Posology and method of administration

The amount of dextrose required can be determined only by continued observation of the patient and repeated checking of the indicators (systemic arterial and venous pressures, urinary output, etc.).

Dosage may (where time permits) be estimated by measuring the concentration of one of the extracellular fluid constituents (e.g. serum protein) and taking the increment over the normal value as an indication to the water deficit.

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS 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 % (20 ml) INJECTION FRESENIUS should be administered via a central vein. When used for the emergency treatment of hypoglycaemia, DEXTROSE 50 % (20 ml) INJECTION FRESENIUS may be administered slowly into a peripheral vein at a rate not greater than 3 ml per minute.

4.3 Contraindications

The use of DEXTROSE 50 % (20 ml) INJECTION FRESENIUS is contraindicated in patients with:

- hypersensitivity to the dextrose (glucose) or to any excipients listed in section 6.1, or known allergy to maize or maize products
- anuria, intracranial or intraspinal haemorrhage
- delirium tremens where there is dehydration.
- acute ischaemic strokes, as hyperglycaemia has been implicated in increasing cerebral ischaemic brain damage and in impairing recovery
- glucose-galactose malabsorption syndrome.

4.4 Special warnings and precautions for use

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS should be administered via a large central vein and administered slowly to minimise damage at the site of injection.

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS should be used with caution in patients with overt or known subclinical diabetes mellitus, carbohydrate intolerance for any reason, severe

undernutrition, thiamine (vitamin B1) deficiency, hypophosphataemia, haemodilution, sepsis, trauma, shock, metabolic acidosis or severe dehydration.

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS can be a sclerosing substance and could cause thrombosis. Monitor blood glucose, potassium and sodium levels.

Rapid administration of hypertonic glucose 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 glucose should be monitored.

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS should be administered with care to patients with diabetes insipidus.

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS tolerance may be impaired in patients with renal failure or kidney damage.
DEXTROSE 50 % (20 ml) INJECTION FRESENIUS intravenous infusion is a hypertonic solution (*in vitro*, in a container). In the body, however, glucose-containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolism (see section 5.2).

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 metabolise glucose, intravenous administration of glucose can cause:

- electrolyte disturbances such as:
    - hypo- or hyperosmotic hyponatraemia.

Hypoosmotic hyponatraemia:

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

Fluid and acid base balance, serum glucose, serum sodium, and other electrolytes may need to be monitored before and during administration, especially in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonists, due to the risk of hyponatraemia.

Monitoring of serum sodium is particularly important for physiologically hypotonic fluids (*in vivo* tonicity). DEXTROSE 50 % (20 ml) INJECTION FRESENIUS may become extremely hypotonic after administration due to glucose metabolism in the body (see sections 4.4, 4.5, 4.8 and 5.2).

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

Children (≤ 16 years of age), women of childbearing potential, patients with hypoxaemia, 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 (see sections 4.2 and 4.8).

4.5 Interaction with other medicines and other forms of interaction

Medicine increasing vasopressin effect, listed below, leads to reduced renal electrolyte free water excretion and increases the risk of hospital- acquired hyponatraemia following inappropriately.
balanced treatment with intravenous fluids (see sections 4.2, 4.4 and 4.8):

- medicines stimulating vasopressin release, e.g. carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3,4-methylenedioxy-*N*-methamphetamine, ifosfamide, antipsychotics, narcotics
- medicine potentiating vasopressin action, e.g. nonsteroidal anti-inflammatory drugs (NSAIDs), cyclophosphamide
- vasopressin analogues, e.g. desmopressin, oxytocin, vasopressin, terlipressin.

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

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

Intravenous DEXTROSE 50 % (20 ml) INJECTION FRESENIUS may result in fetal insulin production, with an associated risk of rebound hypoglycaemia in the neonate.

Infusions of DEXTROSE 50 % (20 ml) INJECTION FRESENIUS administered during Caesarean section and labour should not exceed 5 – 10 g dextrose/hour.

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS should be administered with special caution to pregnant women during labour, particularly if administered in combination with oxytocin, due to the risk of hyponatraemia (see sections 4.4, 4.5 and 4.8).

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

System organ class (SOC)	**Adverse reaction (MedDRA term)**	**Frequency**

System organ class (SOC)	Adverse reaction (MedDRA term)	Frequency
Metabolism and nutrition disorders	Hospital-acquired hyponatraemia*, hyperglycaemia**, hypokalaemia, hypophosphataea, hypomagnesaemia, fluid and electrolyte imbalance, glucosuria**	Not known***
Nervous system disorders	Hyponatraemic encephalopathy*	Not known
Vascular disorders	Thrombosis	Not known
General disorders and administration site conditions	Pain at the injection site, vein irritation, venous thrombosis, phlebitis, thrombophlebitis and tissue necrosis (following extravasation).	Not known

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

** 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.

*** Frequency unknown cannot be estimated from the available data.

When administered slowly, in small doses, acidosis, alkalosis, hypoglycaemia (after infusion), hyperglycaemia (during infusion), hyperosmolar syndrome (mental confusion, loss of consciousness), hypokalaemia, hypovitaminosis and thrombosis may occur.

The administration of DEXTROSE 50 % (20 ml) INJECTION FRESENIUS 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 undernutrition.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of DEXTROSE 50 % (20 ml) INJECTION FRESENIUS is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Treatment is symptomatic and supportive.

Overdose of dextrose may lead to hyperglycaemia and glycosuria, leading to dehydration, hyperosmolar coma and death.

In the event of overdose of dextrose, it may be necessary to administer appropriate doses of insulin.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 24 Mineral substitutes, electrolytes and trace elements.

Pharmacotherapeutic group: Solutions for parenteral nutrition, carbohydrates.

ATC code: B05BA03

Dextrose may be used to adjust the osmotic pressure of dialysis fluids and injections.

The metabolism of glucose (dextrose) is an energy source for the body.

5.2 Pharmacokinetic properties

Dextrose is rapidly metabolised into carbon dioxide and water.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid (for pH-adjustment)

Water for injection.

6.2 Incompatibilities

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS should not be administered concomitantly with blood through the same infusion set, because of the possibilities of agglomeration.

Do not add certain medicine to the solution for injection with which it is incompatible, e.g. warfarin sodium, vitamin B12, sodium bicarbonate, kanamycin sulphate and novobiocin sodium.

6.3 Shelf life

60 months.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

20 ml type I clear, glass OPC ampoules, packed into PVC blister tray and outer carton (10 x 20 ml).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Use as directed by the medical practitioner.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten 6020,

Gqeberha

South Africa

8. REGISTRATION NUMBER

V/24/222

9. DATE OF FIRST AUTHORISATION

September 1989

10. DATE OF REVISION OF THE TEXT

14 December 2023