APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

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

Dextrose (anhydrous)

Contains sugar (dextrose).

Read all of this leaflet carefully before you are given DEXTROSE 50 % (20 ml) INJECTION FRESENIUS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What DEXTROSE 50 % (20 ml) INJECTION FRESENIUS is and what it is used for
2. What you need to know before you are given DEXTROSE 50 % (20 ml) INJECTION FRESENIUS
3. How to receive DEXTROSE 50 % (20 ml) INJECTION FRESENIUS
4. Possible side effects
5. How to store DEXTROSE 50 % (20 ml) INJECTION FRESENIUS
6. Contents of the pack and other information.

1. What DEXTROSE 50 % (20 ml) INJECTION FRESENIUS is and what it is used for

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS is a concentrated solution of dextrose (a type of sugar, also known as glucose).

Dextrose is the main form of carbohydrate used by the human body and is administered intravenously in emergency situations involving conditions such as hypoglycaemia (too low blood sugar) or insulin-caused hypoglycaemic coma (it is a too low blood sugar content, caused by too much insulin, which may result in loss of consciousness).

2. What you need to know before you are given DEXTROSE 50 % (20 ml) INJECTION FRESENIUS

You should not be given DEXTROSE 50 % (20 ml) INJECTION FRESENIUS:

- if you are allergic (hypersensitive) to dextrose (glucose) or any of the other ingredients of DEXTROSE 50 % (20 ml) INJECTION FRESENIUS (listed in section 6)
- if you are allergic (hypersensitive) to maize or maize products
- if your kidneys fail to produce urine or if you have kidney failure
- if you have bleeding inside your skull or spine
- if you have a condition known as delirium tremens (uncontrolled bouts of shaking after stopping drinking alcohol)
- if you have had a stroke
- if your body can not absorb the sugars known as glucose and galactose.

Warnings and precautions

Special care should be taken with DEXTROSE 50 % (20 ml) INJECTION FRESENIUS.

Tell your doctor or health care provider before being given DEXTROSE 50 % (20 ml) INJECTION FRESENIUS:

- if you have diabetes (high blood sugar)
- if you have an intolerance to carbohydrates
- if you are undernourished
- if you have low levels of thiamine (vitamin B1) or phosphates (a mineral) in your blood
- if you suffer from haemodilution (an increase in the fluid content of blood, leading to a lower concentration of red blood cells)

- if you have sepsis (serious infection)
- if you suffer from trauma or shock
- if you have metabolic acidosis (build-up of acid in your body due to kidney failure)
- if you are severely dehydrated (extreme thirst)
- if you have signs of mental confusion or are unconscious
- if you have chronic uraemia (a chronic kidney disease with high levels of urea in your blood)
- if you are receiving DEXTROSE 50 % (20 ml) INJECTION FRESENIUS for a long period
- if you have diabetes insipidus (extreme thirst, excessive amounts of urine, colourless urine instead of pale yellow)
- if your kidneys are not functioning normally.

If you are acutely ill, have pain, post-operative stress, infections, burns, diseases of your central nervous system, heart, liver and kidney and if you are on medicines increasing the effect of vasopressin (a hormone which regulates the amount of body fluids), you are at particular risk of developing acute hyponatraemia (abnormally low level of sodium in your blood) when given DEXTROSE 50 % (20 ml) INJECTION FRESENIUS).

Acute hyponatraemia can lead to 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, women of childbearing potential and patients with meningitis or brain bleeding are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

Other medicines and DEXTROSE 50 % (20 ml) INJECTION FRESENIUS

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS should not be given through the same infusion equipment as whole blood, as the dextrose can mix with the blood, and clumping can occur.

Health care providers should not add the following medicine to DEXTROSE 50 % (20 ml) INJECTION FRESENIUS with which it is incompatible:

- warfarin (helps prevent a blood clot from forming)
- vitamin B12 (used as a supplement)
- sodium bicarbonate (used to relieve heartburn or acid indigestion)
- kanamycin or novobiocin (used to treat serious bacterial infections).

The following medicines, which increase the effect of vasopressin and the risk of a low sodium level (hyponatraemia), may have an interaction with DEXTROSE 50 % (20 ml) INJECTION FRESENIUS:

- carbamazepine and oxcarbazepine (used to treat epilepsy)
- vincristine and ifosfamide (used as anticancer treatments)
- cyclophosphamide (used to treat cancer and autoimmune diseases)
- selective serotonin reuptake inhibitors (used to treat depression)
- the recreational drug ‘ecstasy’ (MDMA)
- antipsychotics (used for mental health disorders)
- narcotics (used to treat severe pain or as an anaesthetic before surgery)
- nonsteroidal anti-inflammatory drugs (NSAIDs, used to treat pain and inflammation)
- desmopressin (used to treat diabetes insipidus – extreme thirst, excessive amounts of urine, colourless urine instead of pale yellow)
- oxytocin (used during labour)
- vasopressin and terlipressin (used to treat bleeding oesophageal varices – enlarged veins in your food pipe caused by liver problems)
- diuretics or water tablets (medicines which increase the amount of urine).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving DEXTROSE 50 % (20 ml) INJECTION FRESENIUS.

Safety in pregnancy and breastfeeding has not been established.

Driving and using machines

There is no information on the effects of DEXTROSE 50 % (20 ml) INJECTION FRESENIUS on your ability to drive a vehicle or operate heavy machinery. The condition for which you are receiving the injection may however impair your ability to drive a vehicle or operate heavy machinery.

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS contains sugar (dextrose).

Contains 10 g dextrose per 20 ml solution for injection.

This should be taken into account in patients with diabetes mellitus.

3. How to receive DEXTROSE 50 % (20 ml) INJECTION FRESENIUS

You will not be expected to administer DEXTROSE 50 % (20 ml) INJECTION FRESENIUS to yourself. Your doctor or health care provider will administer DEXTROSE 50 % (20 ml) INJECTION FRESENIUS to you for a specific condition.

Your doctor will decide what dosage, how often and how long you will receive DEXTROSE 50 % (20 ml) INJECTION FRESENIUS. This depends on your condition and other factors, such as your blood pressure and the amount of urine excreted.

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS should not be given through the same infusion equipment as whole blood.

If you receive more DEXTROSE 50 % (20 ml) INJECTION FRESENIUS than you should

Since a health care provider will administer DEXTROSE 50 % (20 ml) INJECTION FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the symptoms of the overdosage.

If you missed a dose of DEXTROSE 50 % (20 ml) INJECTION FRESENIUS

Since a health care provider will administer DEXTROSE 50 % (20 ml) INJECTION FRESENIUS, it is unlikely that a dose will be missed.

4. Possible side effects

DEXTROSE 50 % (20 ml) INJECTION FRESENIUS can have side effects. Not all side effects reported for DEXTROSE 50 % (20 ml) INJECTION FRESENIUS are included in this leaflet. Should your general health worsen, or you experience any untoward effects while receiving DEXTROSE 50 % (20 ml) INJECTION FRESENIUS, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop administration of DEXTROSE 50 % (20 ml) INJECTION FRESENIUS immediately:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to DEXTROSE 50 % (20 ml) INJECTION FRESENIUS. You may need urgent medical attention.

Tell your doctor as soon as possible if you experience any of the following reactions after receiving DEXTROSE 50 % (20 ml) INJECTION FRESENIUS.

Frequency not known:

- Abnormally low sodium level (hyponatraemia) in your blood, which can lead to a serious condition called hospital-acquired hyponatraemia. It may cause irreversible brain damage, due to the development of acute hyponatraemic encephalopathy (brain swelling, with symptoms such as headache, feeling sick (nausea), vomiting, seizures, tiredness and lack of energy).
- Hyperglycaemia (abnormal high levels of sugar in your blood and/or urine). If this happens you may feel tired and confused or lose consciousness. You may also feel thirsty and pass urine more frequently.

- Fluid and electrolyte imbalance.
- Pain and irritation at the injection site.
- Inflammation of the vein with formation of a clot (phlebitis).
- Low levels of potassium (hypokalaemia), magnesium (hypomagnesaemia) and phosphates (hypophosphataemia) in the blood, which will be indicated by blood tests.
- Dehydration (thirsty, dry mouth, tiredness, light-headedness).
- Glucose in the urine (extreme hunger or thirst, more frequent urination).
- Vein clots (thrombosis), inflammation of the veins, local pain or irritation at the infusion site.

If you are administered DEXTROSE 50 % (20 ml) INJECTION FRESENIUS and you have low levels of thiamine (vitamin B1) in your blood, you may develop Wernicke's encephalopathy (a condition where you may feel confused and unsteady on your feet).

If you are administered DEXTROSE 50 % (20 ml) INJECTION FRESENIUS and you are severely undernourished, your body may retain water and salt, your skin may swell, you may have difficulty in breathing, and you may experience heart failure.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DEXTROSE 50 % (20 ml) INJECTION FRESENIUS.

5. How to store DEXTROSE 50 % (20 ml) INJECTION FRESENIUS

- Store at or below 25 °C.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Unused portions of the solution should be discarded.

6. Contents of the pack and other information

What DEXTROSE 50 % (20 ml) INJECTION FRESENIUS contains

The active ingredient is dextrose anhydrous.

The other ingredients are hydrochloric acid (for pH-adjustment) and water for injection.

What DEXTROSE 50 % (20 ml) INJECTION FRESENIUS looks like and contents of the pack

Clear, colourless to straw-coloured solution for injection.

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

Holder of Certificate of Registration and Manufacturer

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten 6020

Gqeberha

South Africa

Tel: + 27 41 403 1600

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