Approved Patient Information Leaflet for DEXTROSE 20 % and 35 % FRESENIUS

SCHEDULING STATUS S3

DEXTROSE 20 % FRESENIUS solution for infusion

DEXTROSE 35 % FRESENIUS solution for infusion

Dextrose (anhydrous) (as dextrose monohydrate)

Contains sugar (dextrose).

Read the entire leaflet carefully before you are given DEXTROSE 20 % and 35 % FRESENIUS solution

- 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 20 % and 35 % FRESENIUS solution is and what it is used for

DEXTROSE 20 % and 35 % FRESENIUS solution is a hypertonic solution, used in adults and children as a source of energy.

2. What you need to know before you are given DEXTROSE 20 % and 35 % FRESENIUS solution

Do not receive DEXTROSE 20 % and 35 % FRESENIUS solution:

- if you are allergic (hypersensitive) to dextrose (glucose) or any of the other ingredients of DEXTROSE 20 % and 35 % FRESENIUS solution (listed in section 6)
- if you are allergic to maize or maize products
- if your kidneys fail to produce urine or if you have kidney failure
- if you have bleeding inside the skull or spine
- if you have had a stroke
- if you have a condition known as delirium tremens (uncontrolled bouts of shaking after stopping drinking alcohol)
- if you are dehydrated
- if your body can not absorb the sugars known as glucose and galactose.

Warnings and precautions

Tell your doctor or health care provider before being given DEXTROSE 20 % and 35 % FRESENIUS solution:

- if you have suffered an acute stroke caused by a blockage in an artery that supplies blood to the brain, as high blood glucose levels can increase the chance of brain damage and impair recovery
- 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 have sepsis (serious infection)
- if you suffer from trauma or shock
- 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 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 20 % and 35 % FRESENIUS solution.

Acute hyponatraemia can lead to encephalopathy (swelling of the brain), characterised by headache, nausea, seizures, lethargy, and vomiting. Patients with brain swelling (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 20 % and 35 % FRESENIUS solution

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

If any other injectable medicines are added to the solution for infusion, your doctor or health care provider will inspect the final solution for cloudiness or precipitation before it is administered to you.

The following medicines, which increase the effect of vasopressin and the risk of a low sodium level (hyponatraemia), may have an interaction with DEXTROSE 20 % and 35 % FRESENIUS solution:

- 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)
- nonsteroidal anti-inflammatory drugs (NSAIDs, used to treat pain and inflammation)
- desmopressin (used to treat diabetes insipidus – extreme thirst and the continuous production of large volumes of dilute urine)

- 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 20 % and 35 % FRESENIUS solution.

Safety in pregnancy and lactation has not been established.

Driving and using machines

Your doctor will decide when to release you from hospital. DEXTROSE 20 % and 35 % FRESENIUS solution should not affect your ability to drive a vehicle and use machines, however, ask your doctor if you are fit enough to drive or operate machines after release from hospital.

DEXTROSE 20 % and 35 % FRESENIUS solution contains dextrose

DEXTROSE 20 % FRESENIUS solution contains 100 g dextrose per 100 ml solution for infusion.

DEXTROSE 35 % FRESENIUS solution contains 175 g dextrose per 100 ml solution for infusion.

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

3. How DEXTROSE 20 % and 35 % FRESENIUS solution will be administered

DEXTROSE 20 % and 35 % FRESENIUS solution is administered in hospital, by a doctor or health care provider. He/she will ensure that the seal is intact, and that the solution is clear and without visible particles, before giving DEXTROSE 20 % and 35 % FRESENIUS solution to you.

Your health care provider will further dilute DEXTROSE 20 % and 35 % FRESENIUS solution before administering it to you.

Dosage:

DEXTROSE 20 % and 35 % FRESENIUS solution will be slowly infused (dripped) into a vein. Your doctor will determine your dose or your child's dose, the rate at which DEXTROSE 20 % and 35 % FRESENIUS solution is infused into your veins and for how long this should continue. The dose will depend on your body mass, or your child's body mass, medical condition, response on treatment and the laboratory results.

You will be carefully monitored, and your dose adjusted according to the results of your blood tests.

If you receive more DEXTROSE 20 % and 35 % FRESENIUS solution than you should

Since a health care provider will administer DEXTROSE 20 % and 35 % FRESENIUS solution, 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 20 % and 35 % FRESENIUS solution

Since a health care provider will administer DEXTROSE 20 % and 35 % FRESENIUS solution, it is unlikely that a dose will be missed.

4. Possible side effects

DEXTROSE 20 % and 35 % FRESENIUS solution can have side effects.

Not all side effects reported for DEXTROSE 20 % and 35 % FRESENIUS solution are included in this leaflet. Should your general health worsen, or you experience any untoward effects while receiving DEXTROSE 20 % and 35 % FRESENIUS solution, please consult your doctor, pharmacist, or other health care provider for advice.

If any of the following happens, stop administration of DEXTROSE 20 % and 35 % FRESENIUS solution 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 20 % and 35 % FRESENIUS solution. You may need urgent medical attention.

Tell your doctor as soon as possible if you experience any of the following reactions after receiving DEXTROSE 20 % and 35 % FRESENIUS solution: *Frequency not known:*

- Infection at the site of injection, fever.
- 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 (a higher-than-normal level of sugar in your blood and there may also be sugar in your 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 (thrombophlebitis).
- 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).

If you are administered DEXTROSE 20 % and 35 % FRESENIUS solution 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 20 % and 35 % FRESENIUS solution 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 20 % and 35 % FRESENIUS solution.

Health care providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store DEXTROSE 20 % and 35 % FRESENIUS solution

Store at or below 25 °C.

Store all medicines out of reach of children.

Your health care provider will always inspect a container for intactness of the seals and the solution for injection for discolouration or presence of any visible particles. The solution will not be used if it is not clear, if it has visible particles, or if the seals of the bag are not intact.

After mixing, the final infusion solution will be inspected by the health care provider for cloudiness or precipitation immediately after mixing, prior to administration and periodically during administration.

Do not use after the expiry date stated on the bag.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What DEXTROSE 20 % and 35 % FRESENIUS solution contains

The active substance:

DEXTROSE 20 % FRESENIUS solution: Each 500 ml contains 100 g dextrose.

DEXTROSE 35 % FRESENIUS solution: Each 500 ml contains 175 g dextrose.

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

What DEXTROSE 20 % and 35 % FRESENIUS solution looks like and contents of the pack

A clear, colourless solution. May not be more than faintly straw-coloured.

500 ml & 1 000 ml PVC/Freeflex bag.

Not all pack sizes may be marketed.

Holder of Certificates of Registration and Manufacturer

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten 6020

Gqeberha

South Africa

Tel: 041 403 1600

This leaflet was last revised in

11 November 2022

Registration numbers

DEXTROSE 20 % FRESENIUS: L/24/329

DEXTROSE 35 % FRESENIUS: 29/24/0559