Approved Patient Information Leaflet for DEXTROSE 10 % FRESENIUS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

DEXTROSE 10 % FRESENIUS solution for infusion

Dextrose (anhydrous)

Contains sugar (dextrose).

Read all of this leaflet carefully before you are given DEXTROSE 10 % FRESENIUS

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

What is in this leaflet

1. What DEXTROSE 10 % FRESENIUS is and what it is used for

DEXTROSE 10 % FRESENIUS contains 100 g dextrose (as dextrose anhydrous) per 1 000 ml.

DEXTROSE 10 % FRESENIUS is a hypertonic solution, used in adults and children as a source of calories (energy) for nutrition and water for hydration.

2. What you need to know before you receive DEXTROSE 10 % FRESENIUS

You should not receive DEXTROSE 10 % FRESENIUS if you have:

- an allergy to dextrose, maize or maize products or any other ingredient in DEXTROSE 10 % FRESENIUS (listed in section 6)
- diabetes (high blood sugar) or diabetes insipidus (a disorder of salt and water metabolism characterised by intense thirst and frequent urination)
- hyperosmolar coma (a complication of diabetes mellitus, characterised by excessive thirst, dry mouth or increased urination)
- haemodilution (reduced concentration of red blood cells, characterised by confusion, nausea, vomiting or seizures)
- hyperhydration (leads to dangerously low levels of sodium in your blood, causing more severe symptoms, such as muscle weakness, spasms, cramps or seizures)
- hypervolaemia (too much fluid in the blood, characterised by increased body mass, swelling and shortness of breath)
- hyperlactataemia (characterised by the build-up of lactate causing an excessively low pH to develop in the bloodstream)

- severe kidney failure (characterised by no output of urine (anuria)
- heart failure
- excess fluid in the lungs, brain or stomach area (ascites), causing swelling (oedema)
- other known glucose intolerances (including metabolic conditions that result in higher than normal blood glucose levels)
- bleeding inside your skull or spinal cord
- a severe form of alcohol withdrawal and you are dehydrated
- dehydration (lack of water or fluid)
- glucose-galactose malabsorption syndrome.

If possible, tell your doctor if any of the above applies to you or your child before DEXTROSE 10 % FRESENIUS is administered.

Warnings and precautions

Take special care with DEXTROSE 10 % FRESENIUS

Tell your doctor if any of the below conditions apply to you or your child before DEXTROSE 10 % FRESENIUS is used:

- If you have diabetes, malnutrition, thiamine (vitamin B1) deficiency, carbohydrate intolerance, sepsis, shock or trauma. Rapid infusion may cause a high blood sugar concentration.
- If you have impaired kidney function or urinary tract obstruction. Dextrose tolerance may be impaired in patients with kidney failure.
- If you have been diagnosed with cardiac decompensation (inability of the heart to maintain adequate circulation).
- If you have hypervolaemia (too much fluid in the blood).
- If you recently had acute ischaemic stroke (when an artery in the brain becomes blocked) or brain injury.

- In infants of low birth mass. Your doctor or health care provider will ensure that DEXTROSE 10 % FRESENIUS is not administered too rapidly and that too high volumes are not infused, as it may possibly result in bleeding in the brain.
- Electrolyte and fluid balance are easily disturbed in pre-term babies. Your doctor will ensure that fluid intake, urine output and serum electrolytes are monitored closely.

Your doctor will ensure that sufficient sodium and potassium are added, particularly in patients on digoxin therapy.

Using other medicines with DEXTROSE 10 % FRESENIUS

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 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 10 % 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

Safety during pregnancy and breastfeeding has not been established.

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 10 % FRESENIUS.

Your doctor will inform you about the potential risks to your baby and will only consider DEXTROSE 10 % FRESENIUS if the expected benefits outweigh any potential risk to your baby.

Driving and using machines

After receiving DEXTROSE 10 % FRESENIUS your ability to drive and use machines should not be compromised. Your doctor will decide when you can be discharged from the hospital or clinic.

DEXTROSE 10 % FRESENIUS contains sugar (dextrose).

Contains 100 g dextrose per 1 000 ml solution for infusion.

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

3. How DEXTROSE 10 % FRESENIUS will be administered

You will not be expected to give yourself DEXTROSE 10 % FRESENIUS.

It will be given to you by a person who is qualified to do so.

DEXTROSE 10 % FRESENIUS will be slowly infused (dripped) into a vein through a small bore needle.

Your doctor will determine your or your child's dose, the rate at which it is infused and for how long this should be continued. You will be carefully monitored and your dose adjusted according to your or your child's medical condition, body mass and response.

If you are elderly, you are more likely to have decreased renal function and your doctor will carefully select the correct dose and may also monitor your renal function.

If you receive more DEXTROSE 10 % FRESENIUS than you should

Since a health care provider will administer DEXTROSE 10 % FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you have any further questions on the use of DEXTROSE 10 % FRESENIUS, ask your doctor, health care provider or pharmacist for more information.

If you missed a dose of DEXTROSE 10 % FRESENIUS

Since a health care provider will administer DEXTROSE 10 % FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

DEXTROSE 10 % FRESENIUS can have side effects.

Not all side effects reported for DEXTROSE 10 % FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DEXTROSE 10 % FRESENIUS, please consult your doctor, pharmacist or other health care provider for advice.

Tell your doctor or health care provider immediately if you notice the following:

Frequency not known:

- 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 10 % FRESENIUS. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequency not known:

- Pain, vein irritation, vein inflammation with clot formation, or swelling at the injection site during or immediately after the injection.
- Disturbance in electrolyte balance. Your doctor may order regular blood tests to make sure that salts such as sodium, magnesium, potassium and phosphates are present in the correct concentration in your blood.
- Hyponatraemic encephalopathy (central nervous system dysfunction, characterised by headache, nausea, vomiting, disturbed state of mind, confusion, stupor, tremor and

seizures).

- Sweating and skin rash.
- Chills, shivering, fever, infection at the site of infusion.
- Swelling and water overload from too rapid or prolonged duration of infusion.
- Hyperglycaemia (too much sugar in the blood). This may also increase urinary output with loss of fluid and electrolytes.

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

Reporting of side effects:

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.

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the **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 10 % FRESENIUS.

5. How to store DEXTROSE 10 % FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 °C.

Your health care provider will always inspect containers for intactness of seals and the solution for infusion for discolouration or presence of any visible particulate matter. He or she will not use it if the solution is not clear or if the seals are not intact.

If other additives are also prescribed, the final infusion solution will also be inspected by the health care provider for cloudiness or precipitation immediately after mixing, prior to administration and periodically during administration.

6. Contents of the pack and other information

What DEXTROSE 10 % FRESENIUS contains:

The active substance is dextrose (anhydrous).

Other ingredients are hydrochloric acid (for adjustment to pH 4,5), sodium hydroxide (for adjustment to pH 4,5) and water for injection.

What DEXTROSE 10 % FRESENIUS looks like and contents of the pack:

Sterile, clear, colourless solution.

1 000 ml PVC or **free***flex*® bag.

Pack sizes: 12.

Not all container closure systems may be marketed.

Holder of Certificate of Registration and Manufacturer:

Fresenius Kabi Manufacturing SA (Pty) Ltd

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