Approved Patient Information Leaflet for DEXTROSE 5 % FRESENIUS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

DEXTROSE 5 % FRESENIUS solution for infusion

Dextrose (anhydrous)

Contains sugar (dextrose).

Read the entire leaflet carefully before you are given DEXTROSE 5 % 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

6. Contents of the pack and other information.

1. What DEXTROSE 5 % FRESENIUS is and what it is used for

DEXTROSE 5 % FRESENIUS contains 50 g dextrose (as dextrose monohydrate) per 1 000 ml.

DEXTROSE 5 % FRESENIUS solution is used in adults and children as a source of calories (energy) for nutrition and water for hydration.

It is also used to dilute or to deliver other medicines that can be given by infusion.

2. What you need to know before you receive DEXTROSE 5 % FRESENIUS

You should not receive DEXTROSE 5 % FRESENIUS if you:

- have an allergy to dextrose or any other ingredient in DEXTROSE 5 % FRESENIUS (listed in section 6)
- have an allergy to maize or maize products
- have the glucose-galactose malabsorption syndrome
- have been told that you have high levels of lactate in the blood
- have diabetes that is not adequately treated, allowing your blood sugar levels to rise above normal (uncompensated diabetes)
- have states of glucose intolerance, for example:
  when your body's metabolism does not function correctly, e.g. due to severe illness (metabolic stress)
- have the following condition: hyperosmolar coma (unconsciousness). This is a type of coma that can occur if you have diabetes and do not receive enough medicine.
- have a higher amount of sugar in the blood than normal (hyperglycaemia)
- have a higher level of lactate in the blood than normal (hyperlactataemia).

If possible, tell your doctor if any of the above applies to you before you receive DEXTROSE 5 % FRESENIUS.

Warnings and precautions

Take special care with DEXTROSE 5 % FRESENIUS.

Tell your doctor if any of the below conditions apply to you or your child before DEXTROSE 5 % FRESENIUS is used:

- if you have recently had an operation
- if you have been bleeding inside your skull or spine
- 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 recently had a stroke (an artery in the brain became blocked)
- if you have impaired kidney function or urinary tract obstruction. Dextrose tolerance may be impaired in patients with kidney failure
- if you suffer from alcoholism
- if you are dehydrated (lack of water or fluid)
- if you have hypervolaemia (too much fluid in the blood).

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.

Using other medicines with DEXTROSE 5 % FRESENIUS

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

Tell your doctor if you are on corticosteroid (cortisone) treatment or if you take or use dopamine, epinephrine (adrenaline) or norepinephrine (noradrenaline).

The following medicines, which increase the effect of vasopressin and the risk of a low sodium level (hyponatraemia), may have an interaction with DEXTROSE 5 % 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 5 % FRESENIUS.

Your doctor will inform you about the potential risks to your baby and will only consider DEXTROSE 5 % FRESENIUS if the expected benefits outweigh any potential risk to your baby.

Driving and using machines

After receiving DEXTROSE 5 % 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 5 % FRESENIUS contains sugar (dextrose).

Contains 50 g dextrose per 1 000 ml solution for infusion.

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

3. How DEXTROSE 5 % FRESENIUS will be administered

You will not be expected to give yourself DEXTROSE 5 % FRESENIUS.

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

DEXTROSE 5 % 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 given too much or too little DEXTROSE 5 % FRESENIUS

Since a health care provider will administer DEXTROSE 5 % 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 5 % FRESENIUS, ask your doctor, health care provider or pharmacist for more information.

If you forget to use DEXTROSE 5 % FRESENIUS

Since a health care provider will administer DEXTROSE 5 % FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

DEXTROSE 5 % FRESENIUS can have side effects.

Not all side effects reported for DEXTROSE 5 % FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DEXTROSE 5 % 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:

- 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 5 % FRESENIUS. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Pain, vein irritation, vein inflammation with clot formation, or swelling at the injection site during or immediately after the injection.
- Passing abnormally large volumes of dilute urine.
- High concentration of sugar in the blood. This may increase urinary output with loss of fluid and electrolytes and you may feel thirsty, tired and confused.
- Disturbance in electrolyte (mineral salts) balance. Your doctor may order regular blood tests to check your sodium, magnesium, potassium and phosphates concentrations.
- Swelling and water overload (your skin may swell and you may have difficulty breathing).

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 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 5 % FRESENIUS.

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 5 % FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 ºC.

DEXTROSE 5 % FRESENIUS will be appropriately stored in the hospital ward or dispensary.

6. Contents of the pack and other information

What DEXTROSE 5 % FRESENIUS contains:

The active substance is dextrose (as dextrose monohydrate).

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

What DEXTROSE 5 % FRESENIUS looks like and contents of the pack:

Clear, colourless solution.

50 ml PVC/**free***flex*® bag

100 ml PVC/**free***flex*® bag or KabiPac (PE) bottle

200 ml PVC bag

250 ml **free***flex*® bag or KabiPac (PE) bottle

500 ml PVC/**free***flex*® bag or KabiPac (PE) bottle

1 000 ml PVC/**free***flex*® bag or KabiPac (PE) bottle.

Not all container closure systems and pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer:

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