

Approved Patient Information Leaflet for DEXTROSE 50 % FRESENIUS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

DEXTROSE 50 % FRESENIUS solution for infusion

Dextrose (anhydrous) (as dextrose monohydrate)

Contains sugar (dextrose).

Read the entire leaflet carefully before you are given DEXTROSE 50 % 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 % FRESENIUS is and what it is used for
2. What you need to know before you are given DEXTROSE 50 % FRESENIUS
3. How to receive DEXTROSE 50 % FRESENIUS
4. Possible side effects
5. How to store DEXTROSE 50 % FRESENIUS
6. Contents of the pack and other information.

1. What DEXTROSE 50 % FRESENIUS is and what it is used for

DEXTROSE 50 % FRESENIUS belongs to a group of medicines known as carbohydrate solutions for parenteral nutrition.

Dextrose is a type of sugar also called glucose.

DEXTROSE 50 % FRESENIUS is used to expand blood volume in cases of shock and bleeding, and to counteract dehydration.

2. What you need to know before you are given DEXTROSE 50 % FRESENIUS

You should not be given DEXTROSE 50 % FRESENIUS:

- if you are allergic (hypersensitive) to dextrose (glucose) or any of the other ingredients of DEXTROSE 50 % FRESENIUS (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 your body can't absorb the sugars known as glucose and galactose
- if you are a diabetic.

Warnings and precautions

Special care should be taken with DEXTROSE 50 % FRESENIUS.

Tell your doctor or health care provider before being given DEXTROSE 50 % FRESENIUS:

- 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 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
- 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 50 % 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 % FRESENIUS

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

DEXTROSE 50 % 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.

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 % 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)
- 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 50 % FRESENIUS.

Safety in pregnancy and breastfeeding has not been established.

Driving and using machines

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

3. How to receive DEXTROSE 50 % FRESENIUS

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

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

DEXTROSE 50 % FRESENIUS should not be given through the same infusion equipment as whole blood.

If you receive more DEXTROSE 50 % FRESENIUS than you should

Since a health care provider will administer DEXTROSE 50 % 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 % FRESENIUS

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

4. Possible side effects

DEXTROSE 50 % FRESENIUS can have side effects.

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

If any of the following happens, stop receiving DEXTROSE 50 % FRESENIUS immediately:

- swelling of the hands, feet, ankles, face, lips and 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 % 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 % 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 (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 (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).

If you are administered DEXTROSE 50 % 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 % 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 % 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 50 % FRESENIUS

- Store in a dry place, at or below 25 °C.
- Protect from light.
- 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 % FRESENIUS contains

The active ingredient in DEXTROSE 50 % FRESENIUS is dextrose (as dextrose monohydrate).

Each 50 ml contains 25,0 g dextrose (anhydrous) (as dextrose monohydrate).

Each 100 ml contains 50,0 g dextrose (anhydrous) (as dextrose monohydrate.)

Each 500 ml contains 250,0 g dextrose (anhydrous) (as dextrose monohydrate).

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

What DEXTROSE 50 % FRESENIUS looks like and contents of the pack

DEXTROSE 50 % FRESENIUS solution for infusion is a clear, colourless to straw-coloured solution of anhydrous dextrose in water for injection.

50 ml filled in 100 ml PVC/Freeflex bag

50 ml filled in 50 ml PVC/Freeflex bag

100 ml filled in 100 ml PVC/Freeflex bag

500 ml filled in 500 ml PVC/Freeflex bag

500 ml filled in 1 000 ml PVC/Freeflex bag.

Not all pack sizes may be marketed.

Holder of Certificates of Registration and Manufacturer

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