Approved patient information leaflet for Electrolyte No. 2 with Dextrose 10 % Fresenius

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

Electrolyte No. 2 with Dextrose 10 % Fresenius

Solution for infusion.

Electrolytes and dextrose.

Contains sugar (dextrose).

Sterile and pyrogen free.

Read all of this leaflet carefully before you are given Electrolyte No. 2 with 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 other health care provider.

What is in this leaflet

1. What Electrolyte No. 2 with Dextrose 10 % Fresenius is and what it is used for.
2. What you need to know before you are given Electrolyte No. 2 with Dextrose 10 % Fresenius.
3. How Electrolyte No. 2 with Dextrose 10 % Fresenius is administered.
4. Possible side effects.
5. How to store Electrolyte No. 2 with Dextrose 10 % Fresenius.
6. Contents of the pack and other information.

1. What Electrolyte No. 2 with Dextrose 10 % Fresenius is and what it is used for

Electrolyte No. 2 with Dextrose 10 % Fresenius contains electrolytes and dextrose (a type of sugar) and is used to help manage the fluid, calory and electrolyte balance in your body.

2. What you need to know before you are given Electrolyte No. 2 with Dextrose 10 % Fresenius

Electrolyte No. 2 with Dextrose 10 % Fresenius should not be administered to you:

- if you are hypersensitive (allergic) to any of the ingredients of Electrolyte No. 2 with Dextrose 10 % Fresenius (see section 6);
- if you have severe renal disease, your adrenal glands do not work properly (adrenal insufficiency), or your body produces abnormally low levels of parathyroid hormone (PTH);
- if your kidneys do not function properly and you have difficulty urinating;
- if you have severe blood transfusion reactions (such as fever, chills and hives);
- if your doctor has told you that you have high levels of potassium in your blood (you may experience nausea, fatigue and muscle weakness);
- if you have been diagnosed with heart and lung failure;
- if you have uncontrolled diabetes (high blood sugar), severe high blood glucose levels, or suffer from any glucose intolerance.

Warnings and precautions

Take special care with Electrolyte No. 2 with Dextrose 10 % Fresenius:

- If you are allergic to corn products;
- if you been diagnosed with hypervolaemia (too much fluid in your body);
- if your kidneys do not function normally or you have an obstruction of your urinary tract (causing little or painful urination);
- if you suffer from heart problems;
- if you have diabetes or do not tolerate carbohydrates well;

- if you have been acutely ill, you suffer from pain, post-operative stress, infections, burns, central nervous system diseases, or if you suffer from any heart, liver or kidney disease, you are at particular risk of low sodium levels in your blood after infusion with Electrolyte No. 2 with Dextrose 10 % Fresenius;
- if you have been diagnosed with a swelling on your brain (headache, nausea, seizures, tiredness and vomiting), or you are at risk of developing a swelling on your brain;
- if you are receiving magnesium treatment for conditions such as eclampsia or myasthenia gravis;
- if you suffer from kidney or liver problems;
- if you are severely malnourished.

Your doctor will monitor your heart and potassium levels while you are receiving Electrolyte No.2 with Dextrose 10 % Fresenius.

Other medicines and Electrolyte No. 2 with Dextrose 10 % Fresenius

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

Tell your doctor or pharmacist if you are currently using:

- chlorpropamide, desmopressin (used to treat high blood sugar);
- clofibrate (used to treat high levels of fat in your blood (cholesterol));
- carbamazepine, oxcarbazepine (used to treat seizures);
- vincristine, ifosfamide, cyclophosphamide (used to treat cancer);
- selective serotonin reuptake inhibitors, lithium (used to depression);
- antipsychotics (used to treat mental disorders);
- narcotics (used to treat pain);
- nonsteroidal anti-inflammatory drugs (NSAIDs) (used to treat inflammation and pain);
- oxytocin (hormone used to contract the uterus);

- vasopressin, terlipressin (used to treat low blood pressure);
- diuretics, including amiloride, spironolactone, triamterene (used to treat high blood pressure or excessive fluid in your body);
- corticosteroids, steroids, carbenoxolone (used to treat inflammation or allergic reactions);
- ACE inhibitors, angiotensin II receptors (used to treat high blood pressure);
- tacrolimus, ciclosporin (used to after organ transplants);
- ephedrine, pseudoephedrine (used to treat breathing problems or nasal congestion);
- quinidine (used to treat an irregular heart beat);
- dexamphetamine sulphate, phenfluramine hydrochloride (used as stimulants);
- magnesium (used to treat magnesium muscle cramps).

Pregnancy, breastfeeding and fertility

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 Electrolyte No. 2 with Dextrose 10 % Fresenius is administered.

Safety of Electrolyte No. 2 with Dextrose 10 % Fresenius during pregnancy and breastfeeding has not been established.

Caution is advised with Electrolyte No. 2 with Dextrose 10 % Fresenius while you are giving birth to your baby.

Driving and using machines

Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how Electrolyte No. 2 with Dextrose 10 % Fresenius affects you.

Electrolyte No. 2 with Dextrose 10 % Fresenius contains dextrose and sodium metabisulphite

If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking Electrolyte No. 2 with Dextrose 10 % Fresenius.

Sodium metabisulphite may rarely cause severe hypersensitivity (allergic) reactions and bronchospasm (difficulty breathing).

3. How Electrolyte No. 2 with Dextrose 10 % Fresenius is administered

You will not be expected to give yourself Electrolyte No. 2 with Dextrose 10 % Fresenius. It will be given to you by a person who is qualified to do so.

Electrolyte No. 2 with Dextrose 10 % Fresenius will be administered into your vein. Your doctor will determine the correct dose for you based on your age, weight, clinical condition and blood test results.

If you have the impression that the effect of Electrolyte No. 2 with Dextrose 10 % Fresenius is too strong or too weak, tell your doctor or pharmacist.

If you take more Electrolyte No. 2 with Dextrose 10 % Fresenius than you should

Since a health care professional will administer Electrolyte No. 2 with Dextrose 10 % Fresenius, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

Electrolyte No. 2 with Dextrose 10 % Fresenius can have side effects.

Not all side effects reported for Electrolyte No. 2 with Dextrose 10 % Fresenius are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Electrolyte No. 2 with Dextrose 10 % Fresenius, please consult your health care provider for advice.

If any of the following happens, stop taking Electrolyte No. 2 with Dextrose 10 % Fresenius and tell your doctor immediately:

- swelling of your 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 allergic reaction to Electrolyte No. 2 with Dextrose 10 % Fresenius. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

The following side effects may occur, but the frequency is not known:

- low levels of sodium in your blood (nausea, vomiting, headache, confusion, tiredness, restlessness, muscle weakness or cramps, seizures);
- swelling of your brain due to very low levels of sodium in your body (when water enters the brain cells it results in increased pressure in the skull causing severe headache, nausea, seizures, tiredness and vomiting);
- seizures (fits).

These are all serious effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects may occur, but the frequency is not known:

- high levels of potassium in your blood (chest pain, changes in the way your heart beats, muscle weakness, nausea, vomiting);
- excessive fluid build-up in your body (rapid weight gain, swelling of your arms, hands, legs or feet, shortness of breath, increased blood pressure);
- high levels of sugar in your blood (increased thirst, frequent urination, tiredness);
- injection related side effects like infection at site of injection (fever, red, painful skin), vein irritation or vein inflammation with clot formation, burning sensation or irritation;

- swelling due to fluid retention.

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 or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of Electrolyte No. 2 with Dextrose 10 % Fresenius.

5. How to store Electrolyte No. 2 with Dextrose 10 % Fresenius

- Store at or below 25 °C.
- Keep in the original container until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Electrolyte No. 2 with Dextrose 10 % Fresenius contains

Each 1 000 ml contains:

Sodium chloride	1,8 g
Potassium chloride	1,0 g
Sodium lactate	2,8 g

Potassium phosphate dibasic	1,0 g
Magnesium chloride.$6H_2O$	640 mg
Sodium acid phosphate.$2H_2O$	200 mg
Dextrose monohydrate	110 g
Equivalent to/or:	
Dextrose anhydrous	100 g

Content of electrolytes per 1 000 ml:

Sodium ion	62 mmol
Potassium ion	25 mmol
Magnesium ion	3 mmol
Chloride ion	50 mmol
Lactate	25 mmol
H_2PO_4	7 mmol

Milliosmoles (approx.)	727
Kilojoules	1680
pH (approx.)	5

The other ingredients are glacial acetic acid (for pH-adjustment), sodium metabisulphite (E223) and water for injections.

What Electrolyte No. 2 with Dextrose 10 % Fresenius looks like and contents of the pack

A clear colourless to light straw-coloured solution.

1 000 ml PVC or **free***flex*® bag. Pack size: 1 or 12.

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

Holder of certificate of registration and manufacturer

Fresenius Kabi Manufacturing SA (Pty) Ltd

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Korsten

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