PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

MAINTENANCE SOLUTION FRESENIUS

Each 1 000 ml contains:

Potassium chloride	1,938 g
Sodium chloride	1,5198 g
Dextrose anhydrous	50,0 g or
Dextrose monohydrate	55,0 g.

Content of electrolytes per 1 000 ml:

sodium ion (Na^+)	26 mmol/l
potassium ion (K^+)	26 mmol/l
chloride ion (Cl^-)	52 mmol/l.

Contains sugar (dextrose).

Osmolarity:	382 mOsml/l
pH:	4,5
Energy:	840 kilojoules.

Read the entire leaflet carefully before you are given MAINTENANCE SOLUTION FRESENIUS

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

What is in this leaflet

1. What MAINTENANCE SOLUTION FRESENIUS is and what it is used for
2. What you need to know before you are given MAINTENANCE SOLUTION FRESENIUS
3. How MAINTENANCE SOLUTION FRESENIUS should be given
4. Possible side effects
5. How to store MAINTENANCE SOLUTION FRESENIUS
6. Contents of the pack and other information.

1. What MAINTENANCE SOLUTION FRESENIUS is and what it is used for

MAINTENANCE SOLUTION FRESENIUS is a sterile intravenous solution providing fluid (water), energy in the form of sugar (dextrose) and electrolytes (sodium, potassium and chloride) to the body. Electrolytes are substances that become ions in solutions. Electrolytes are present in the human body. Maintenance of the correct electrolyte balance is essential for normal functioning of cells and organs.

MAINTENANCE SOLUTION FRESENIUS may be used intravenously to provide salts, energy and water to patients.

2. What you need to know before you are given MAINTENANCE SOLUTION FRESENIUS

You should not be given MAINTENANCE SOLUTION FRESENIUS:

- if you are hypersensitive (allergic) to potassium chloride, sodium chloride, dextrose or any of the other ingredients of MAINTENANCE SOLUTION FRESENIUS (listed in section 6)
- if you are allergic to maize products, as dextrose may be manufactured from maize products
- if your body is retaining too much fluid
- if you have too much potassium in your blood
- if your kidneys are not functioning normally, and you fail to produce urine or have reduced urine production
- if you have heart and lung problems
- if you have diabetes, too much sugar or lactate in the blood.

Warnings and precautions

Tell your doctor or healthcare provider before being given the infusion:

- if you have low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma (hyponatraemia)
- if you have heart problems or hypertension
- if you have swelling (oedema) and salt (sodium) retention
- if you have high levels of potassium in the blood (hyperkalaemia)
- if you have kidney failure and other kidney problems
- if you have liver problems
- if you have low levels of calcium in the blood (hypocalcaemia)

- if you have carbohydrate intolerance or diabetes
- if you are pregnant or suffer from pre-eclampsia, a pregnancy complication characterised by high blood pressure (see "**Pregnancy and breastfeeding**").

Too much MAINTENANCE SOLUTION FRESENIUS may cause congestion (swelling) of the lungs and limbs. Your doctor will examine you and do regular blood tests to decide how much and for how long you have to receive the treatment.

Other medicines and MAINTENANCE SOLUTION FRESENIUS

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

Make sure that your doctor knows if you are also receiving the following:

- Medicines used for high blood pressure (such as angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor antagonists and terlipressin).
- Medicines used to suppress the immune system (such as tacrolimus and ciclosporin).
- Medicines used for inflammation, asthma or arthritis (called corticosteroids, such as prednisolone).
- A hormone called corticotropin that also occurs naturally in the body, which may be used as part of a medical test to check the functioning of your adrenal glands.
- Medicines used for swelling, known as potassium-sparing diuretics (such as amiloride, spironolactone, triamterene, alone or in combination).
- Medicines used for high blood sugar (such as chlorpropamide).
- Medicines used to treat epilepsy (such as carbamazepine).
- Medicines used to treat high levels of fat (cholesterol) in the blood (such as clofibrate).
- Cancer medicines (such as vincristine, ifosfamide and cyclophosphamide).

- Medicines used to treat depression (also known as selective serotonin reuptake inhibitors [SSRIs]) and mental health problems.
- Medicines used to treat hyperactivity, also known as ADHD (such as methamphetamine).
- Medicines used for pain and inflammation, also known as NSAIDs.
- Medicine used for bed-wetting, called desmopressin.
- Medicines used during labour (oxytocin).
- Medicine used to manage anti-diuretic hormone deficiency and diabetes insipidus, known as vasopressin.

Ask your doctor, pharmacist or professional healthcare provider if you are not sure whether you are using or taking these types of medicines.

Pregnancy and breastfeeding

Safety in 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 healthcare provider for advice before receiving MAINTENANCE SOLUTION FRESENIUS.

When receiving MAINTENANCE SOLUTION FRESENIUS during labour, especially if you are also receiving a medicine called oxytocin, there is a risk of reduced sodium levels in your blood.

If you received MAINTENANCE SOLUTION FRESENIUS while pregnant, your baby may be born with low blood glucose levels.

Driving and using machines

There is no information of the effects of MAINTENANCE SOLUTION FRESENIUS on the ability to drive and use machines. Ask your doctor if you are fit enough to drive or handle machines after release from hospital.

MAINTENANCE SOLUTION FRESENIUS contains dextrose

MAINTENANCE SOLUTION FRESENIUS contains 50 g dextrose anhydrous or 55 g dextrose monohydrate per 1 000 ml solution. This should be taken into account in patients with diabetes mellitus. Dextrose is a type of sugar, manufactured from maize. Tell your doctor if you are allergic to maize products.

3. How you will be given MAINTENANCE SOLUTION FRESENIUS

You will not be expected to administer MAINTENANCE SOLUTION FRESENIUS to yourself. Your doctor or healthcare provider will administer MAINTENANCE SOLUTION FRESENIUS to you for a specific condition. He/she will ensure that the seal is intact, and that the solution is clear and without visible particles before administering MAINTENANCE SOLUTION FRESENIUS to you.

MAINTENANCE SOLUTION FRESENIUS will be slowly infused (dripped) into a vein. Your doctor will determine your dose, the rate at which the medicine is dripped 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 and the laboratory results.

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

If you have the impression that the effect of MAINTENANCE SOLUTION FRESENIUS is too strong or too weak, talk to your doctor or pharmacist.

If you receive more MAINTENANCE SOLUTION FRESENIUS than you should

Since a healthcare provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Too much MAINTENANCE SOLUTION FRESENIUS may cause swelling, high blood sugar levels, or high potassium and salt levels in the blood.

Please tell your doctor or healthcare provider if you have any concerns. He/she will take appropriate supportive measures, if necessary.

If you have any further questions on the use of this product, ask your doctor, healthcare provider or pharmacist for more information.

If you missed a dose of MAINTENANCE SOLUTION FRESENIUS

Since a healthcare provider will administer MAINTENANCE SOLUTION FRESENIUS, it is unlikely that a dose will be missed.

4. Possible side effects

MAINTENANCE SOLUTION FRESENIUS can have side effects.

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

If any of the following happens, your doctor will stop the administration of MAINTENANCE SOLUTION 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 MAINTENANCE SOLUTION FRESENIUS. Your doctor will decide if you may need urgent medical attention.

Tell your doctor immediately if you notice any of the following after receiving MAINTENANCE SOLUTION FRESENIUS:

- Changes in the way your heart beats, such as an irregular heart rhythm.

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you experience any of the following reactions after receiving MAINTENANCE SOLUTION FRESENIUS (frequency unknown):

- Injection site extravasation (the infusion leaks into the tissue or space outside the vein). You may notice burning, stinging, pain or any acute change at the injection site.
- Infection at the site of injection, with fever, vein irritation, vein inflammation with clot formation, bruises or swelling from too much fluid.
- Nausea (feeling sick), vomiting (being sick), stomach pain or diarrhoea (runny tummy).
- Feet and hands feeling numb, feeling weak.
- Feeling confused.
- Low blood pressure (you may feel dizzy, cold and sweaty).
- Seizures or fits.

Your doctor will monitor you or your child for the following, as you may not notice these side effects yourself:

- Too much glucose, potassium or salt in the blood and electrolyte disturbances from unsuitable intravenous use of MAINTENANCE SOLUTION FRESENIUS, or if your kidneys do not function well.

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

Reporting of side effects

Healthcare 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 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 MAINTENANCE SOLUTION FRESENIUS.

5. How to store MAINTENANCE SOLUTION FRESENIUS

- Store at or below 25 °C.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Your professional healthcare 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.
- 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 MAINTENANCE SOLUTION FRESENIUS contains

The active substances are (per 1 000 ml container):

Potassium chloride	1,938 g
Sodium chloride	1,5198 g
Dextrose anhydrous	50,0 g or
Dextrose monohydrate	55,0 g

The other ingredient is water for injection.

What MAINTENANCE SOLUTION FRESENIUS looks like and contents of the pack

MAINTENANCE SOLUTION FRESENIUS for infusion is a clear, colourless to light straw-coloured solution.

1 000 ml PVC or **free***flex*® bags.

Holder of Certificates of Registration and Manufacturer

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This leaflet was last revised in

19 January 2022

Registration number

F/24/65