Approved Patient Information Leaflet for SUSTENANCE FRESENIUS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

SUSTENANCE FRESENIUS solution for infusion

Potassium chloride, sodium chloride, magnesium chloride,

dextrose anhydrous

Contains sugar: Each 1 000 ml solution contains 50 g dextrose anhydrous.

Read all of this leaflet carefully before you receive SUSTENANCE 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 SUSTENANCE FRESENIUS is and what it is used for
2. What you need to know before you receive SUSTENANCE FRESENIUS
3. How to receive SUSTENANCE FRESENIUS
4. Possible side effects
5. How to store SUSTENANCE FRESENIUS
6. Contents of the pack and other information

1. What SUSTENANCE FRESENIUS is and what it is used for

SUSTENANCE FRESENIUS is a sterile intravenous solution providing fluid (water), energy in the form of sugar (dextrose) and electrolytes (sodium, potassium, magnesium 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 function of cells and organs.

SUSTENANCE FRESENIUS may be used to provide salts, energy and fluid volume to your body, or to make your body fluids more alkaline and less acidic.

SUSTENANCE FRESENIUS is given by slow intravenous (into a vein) infusion (drip).

2. What you need to know before you receive SUSTENANCE FRESENIUS

SUSTENANCE FRESENIUS should not be given to you:

- If you are hypersensitive (allergic) to potassium chloride, sodium chloride, magnesium chloride, dextrose or any ingredients of SUSTENANCE FRESENIUS (listed in section 6).
- If you are allergic to maize products, as dextrose may be manufactured from maize products.
- If you are in a current state of hyperglycaemia (high blood sugar).

Warnings and precautions:

Talk to your doctor before receiving SUSTENANCE FRESENIUS if you have:

- heart disease (congestive heart failure)
- respiratory failure (lung disease)
- high blood pressure (hypertension)
- high blood pressure during pregnancy (pre-eclampsia or eclampsia)
- swelling (oedema), particularly around the ankles (peripheral oedema) and salt (sodium) retention
- build-up of fluid in the lungs (pulmonary oedema)
- high levels of potassium (hyperkalaemia)
- kidney failure and other kidney problems

- blood too alkaline (alkalosis)
- liver problems
- aldosteronism (a disease that causes high levels of hormone called aldosterone) any other condition associated with retaining sodium or fluid, such as treatment with steroids
- diabetes (your blood sugar levels will be monitored closely and your insulin treatment may need to be modified)
- any condition that means you are more likely to have high blood levels of potassium (hyperkalaemia), such as kidney failure, adrenocortical insufficiency, severe dehydration (a loss of water from the body, e.g. due to vomiting or diarrhoea) or extensive tissue damage (as can occur in severe burns) – your doctor will need to check your blood potassium levels.
- myasthenia gravis (a disease that causes progressive muscle weakness)
- a head injury within the past 24 hours
- had an operation and are recovering after the operation.
- had a stroke due to a clot in a blood vessel in the brain (ischaemic stroke).

You should also know that:

- Too much SUSTENANCE FRESENIUS may cause congested states (swelling of the lungs and limbs).
- In very low birth weight infants, too much SUSTENANCE FRESENIUS given too quickly may possibly cause bleeding.

Children:

SUSTENANCE FRESENIUS should be given with special care in children. Newborns, especially those born premature and with low birth weight, are at increased risk of developing low or high levels of sugar in the blood (hypo- or hyperglycaemia), which may lead to complications.

Other medicines and SUSTENANCE 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 taking any of the following medicines:

- 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.

SUSTENANCE FRESENIUS with food and drink:

There are no known interactions between SUSTENANCE FRESENIUS, food and drink.

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 health care provider for advice before receiving SUSTENANCE FRESENIUS.

Driving and using machines:

SUSTENANCE FRESENIUS should not affect your ability to drive and use machines. Ask your doctor if you are fit enough to drive or handle machines after release from hospital.

SUSTENANCE FRESENIUS contains dextrose:

SUSTENANCE FRESENIUS contains dextrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Dextrose may be manufactured from maize. You should not receive SUSTENANCE FRESENIUS if you are allergic to maize products. Tell your doctor about this allergy, or if you have an intolerance for certain sugars.

3. How to receive SUSTENANCE FRESENIUS

You will not be expected to give yourself SUSTENANCE FRESENIUS. It will be given to you by a person who is qualified to do so. Your doctor or health care provider will administer SUSTENANCE 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 SUSTENANCE FRESENIUS to you.

SUSTENANCE 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, or your child's age, weight, 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 SUSTENANCE FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

If you receive more SUSTENANCE FRESENIUS than you should:

SUSTENANCE FRESENIUS will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much medicine. Too much SUSTENANCE FRESENIUS may cause swelling and metabolic alkalosis, where your system becomes too alkaline.
Please tell your doctor or healthcare professional if you have any concerns; he/she will take appropriate supportive measures if necessary.

If you missed a dose of SUSTENANCE FRESENIUS:

Since a health care provider will administer SUSTENANCE FRESENIUS it is unlikely that the dose will be missed.

4. Possible side effects

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

If any of the following happens, stop receiving SUSTENANCE FRESENIUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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 SUSTENANCE FRESENIUS. You may need urgent medical attention or hospitalisation.

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

- Seizures (fits).
- An excess of fluid in the body (hypervolaemia).
- High levels of blood potassium which can cause abnormal heart rhythm (hyperkalaemia).
- Low levels of sodium in the blood (hyponatraemia).
- High blood sugar levels (hyperglycaemia).
- Swelling of the brain, which may cause brain injury.

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

Tell your doctor if you experience any of the following:

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.

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

- Too high salt concentration in the blood if your kidneys do not function well.
- Bleeding in brain, in very low birth weight infants.

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 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 SUSTENANCE 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 SUSTENANCE FRESENIUS

Store all medicines out of reach of children**.**

Store at or below 25 ºC.

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 SUSTENANCE FRESENIUS contains:

The active ingredients contained in 1 000 ml of solution are:

Potassium chloride: 1,86 g

Sodium chloride: 2,05 g

Magnesium chloride 0,51 g

Dextrose anhydrous 50 g.

The other ingredient is water for injection.

Ionic concentration:

Sodium	35 mmol/l
Chloride	65 mmol/l
Potassium	25 mmol/l
Magnesium	2,5 mmol/l

pH: 3,5 to 4,5 (approximately).

Osmolarity: 404,5 mOsm/l (approximately).

Energy: 836 kilojoules/l.

What SUSTENANCE FRESENIUS looks like and contents of the pack:

A clear, colourless to light straw-coloured solution.

1 000 ml PVC or **free***flex*® (non-PVC/polyolefine) bags.

Holder of certificate of registration and manufacturer:

Fresenius Kabi Manufacturing SA (Pty) Ltd.

6 Gibaud Road

Korsten

Port Elizabeth 6020

South Africa

Tel.: 041 403 1600

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