**Approved Patient Information Leaflet for POST SURGISOL SOLUTION FRESENIUS**

# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS**

S3

## POST SURGISOL SOLUTION FRESENIUS solution for infusion

**Potassium chloride, sodium chloride, magnesium chloride,**

**dextrose anhydrous**

Contains sugar: Each 1 000 ml solution contains 100 g dextrose anhydrous.

**Read all of this leaflet carefully before you receive POST SURGISOL 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 health care provider.

**What is in this leaflet:**


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

## 1. What POST SURGISOL SOLUTION FRESENIUS is and what it is used for

POST SURGISOL 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.
POST SURGISOL SOLUTION FRESENIUS may be used to provide electrolytes, energy and water to your body, or to make your body fluids more alkaline and less acidic.
POST SURGISOL SOLUTION FRESENIUS is given by slow intravenous (into a vein) infusion (drip).

## 2. What you need to know before you receive POST SURGISOL SOLUTION FRESENIUS

**POST SURGISOL SOLUTION FRESENIUS should not be given to you:**

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

**Warnings and precautions:**

Talk to your doctor before receiving POST SURGISOL SOLUTION FRESENIUS if you have:

- Heart disease (congestive heart failure).
- Respiratory failure (lung disease).
- Kidney failure or other kidney problems.
- High blood pressure (hypertension).
- Swelling (oedema), particularly around the ankles (peripheral oedema) and salt (sodium) retention.
- Build-up of fluid in the lungs (pulmonary oedema).
- High blood pressure during pregnancy (pre-eclampsia or eclampsia).
- Blood too alkaline (alkalosis).

- Liver problems.
- Aldosteronism (a disease that causes high levels of a hormone called aldosterone) or 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).

When you are given POST SURGISOL SOLUTION FRESENIUS, your doctor will take blood and urine samples to monitor:

- The amount of fluid in your body.
- The amount of chemicals such as sodium and potassium in your blood and urine (your plasma and urine electrolytes).
- The amount of sugar in your blood.
- Your acid-base balance (the acidity of the blood and urine).

**Children:**

POST SURGISOL SOLUTION FRESENIUS should be given with special care to children. Newborns, especially those born prematurely 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 POST SURGISOL SOLUTION 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 antidiuretic hormone deficiency and diabetes insipidus, known as vasopressin.

**POST SURGISOL SOLUTION FRESENIUS with food and drink:**

There are no known interactions between POST SURGISOL SOLUTION FRESENIUS, food and drink.

**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 POST SURGISOL SOLUTION FRESENIUS.

The safe use of POST SURGISOL SOLUTION FRESENIUS during pregnancy and breastfeeding has not been established.

**Driving and using machines:**

POST SURGISOL SOLUTION FRESENIUS should not affect your ability to drive and use machines, however, ask your doctor if you are fit enough to drive or handle machines after release from hospital.

**POST SURGISOL SOLUTION FRESENIUS contains dextrose:**

POST SURGISOL SOLUTION 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 POST SURGISOL SOLUTION 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 POST SURGISOL SOLUTION FRESENIUS

You will not be expected to administer POST SURGISOL SOLUTION FRESENIUS to yourself. Your doctor or health care provider will administer POST SURGISOL 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 POST SURGISOL SOLUTION FRESENIUS to you.

POST SURGISOL 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 weight, or your child's body 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 POST SURGISOL SOLUTION FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

**If you receive more POST SURGISOL SOLUTION FRESENIUS than you should:**

Since a health care 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 POST SURGISOL SOLUTION FRESENIUS may cause swelling of the lungs and limbs, high blood sugar levels, or high potassium and salt levels in the blood.

**If you missed a dose of POST SURGISOL SOLUTION FRESENIUS:**

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

## 4. Possible side effects

POST SURGISOL SOLUTION FRESENIUS can have side effects.

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

If any of the following happens, stop receiving POST SURGISOL SOLUTION 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 POST SURGISOL SOLUTION FRESENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following after receiving POST SURGISOL SOLUTION 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.
- Nausea (feeling sick), vomiting (being sick), stomach pain and diarrhoea (runny tummy).

- Feet and hands feeling numb, feeling weak.
- Feeling confused.
- Low blood pressure (you may feel dizzy, cold and sweaty).

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 POST SURGISOL SOLUTION 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 POST SURGISOL SOLUTION FRESENIUS

- Store at or below 25 °C.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

**What POST SURGISOL SOLUTION 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 100 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: 683 mOsm/l (approximately).

Energy: 1 672 kilojoules/l.

**What POST SURGISOL SOLUTION FRESENIUS looks like and contents of the pack:**

Clear, colourless to light straw-coloured solution.

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

Not all pack sizes may be marketed.

**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

**This leaflet was last revised:**

06 October 2021

**Registration number:**

J/24/258

**Date of registration:**

9 March 1977