

**Approved Patient Information Leaflet for  
Sodium Chloride 0,9 % with Dextrose 5 % Fresenius**

**SCHEDULING STATUS**

**S3**

**SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS** solution for infusion

**Sodium chloride**

**Dextrose anhydrous or Dextrose monohydrate**

**Contains sugar: Dextrose (glucose). Each ml contains 50 mg dextrose  
anhydrous or 55 mg dextrose monohydrate.**

**Read all of this leaflet carefully before you are given SODIUM CHLORIDE 0,9 %  
WITH DEXTROSE 5 % 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 SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS is and what it is used for
2. What you need to know before you are given SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS
3. How to receive SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS
4. Possible side effects
5. How to store SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS
6. Contents of the pack and other information.

**1. What SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS is and what it is used for**

SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS is a solution that provides electrolytes from sodium salt, energy from dextrose and fluid from water. It may be used in adults and babies.

**2. What you need to know before you are given SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS**

**You should not be given SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS:**

- if you are hypersensitive (allergic) to maize and maize products
- if you have a known hypersensitivity (allergy) to SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS

SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS may not be given to you when sodium or chloride could be dangerous for your health. However, this infusion will be given to you in a hospital or clinic and your doctor will know if your clinical condition allows you (or your child) to be treated with SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS.

**Warnings and precautions**

**Special care should be taken with SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS:**

**Tell your doctor or healthcare provider before being given the injection:**

- if you have diabetes or carbohydrate intolerance,
- if you have been on a prolonged low potassium diet
- if you are losing water through having loose stools or being sick (vomiting), or from undergoing certain medical procedures

- if you have oedema\* (swelling from too much water in the body) and sodium retention (blood tests show that you have high amounts of sodium in your blood),
- if you have an acid-base imbalance in your blood
- if you have high blood pressure
- if you are pregnant and have high blood pressure
- if you have problems with your adrenal glands which produce certain hormones
- if you have congestive heart failure (inability of the heart to supply sufficient blood flow),
- if you have very weak kidney function or are elderly with kidney problems,
- if you have an infection
- if you have burn wounds
- if you have swelling of the brain (characterised by headache, nausea, fits, abnormal lack of energy and/or vomiting), as you are more at risk of severe, irreversible, and life-threatening brain injury
- if you are suffering from a temporary illness
- if you are in pain
- if you have just had an operation
- if you have brain oedema
- if you are a child or a woman with meningitis or brain bleeding
- if you suffer from severe malnutrition and are severely undernourished
- if you have a shortage of vitamin B1 (thiamine) in your body caused by long-term alcoholism, for example
- if you have inflammation, bleeding or bruising of the brain
- if you suffered a severe brain injury, especially in the first 24 hours following the injury
- if you had a stroke caused by reduced blood flow to the brain

\* Your medical doctor will take the necessary care if he/she determines that you have oedema. This is a condition that causes your body to hold fluids (swelling).

Your medical doctor will also have tests done to see if the potassium concentration in your blood is not too low. SODIUM CHLORIDE 0,9% WITH DEXTROSE 5 % FRESenius, given in excessive amounts, may result in a very low potassium concentration in your blood. Your doctor may want to add some potassium to your treatment.

- if you are elderly with any other disease

### **Children**

- if your baby is a very small infant his/her kidneys may not be able to excrete fluid and salts adequately. Your doctor will ensure that your baby receives the correct amount, that it is dripped in slowly and that regular tests are done.

### **Other medicines and Sodium Chloride 0,9 % with Dextrose 5 % Fresenius**

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

Tell your doctor if you are taking any of the following:

- Chlorpropamide – used to treat high blood sugar (diabetes).
- Clofibrate – used to treat high cholesterol.
- Corticosteroids - used to treat rheumatoid arthritis, inflammatory bowel disease (IBD), asthma, allergies and other conditions.
- Corticotropin – used to treat hormone problems.
- Desmopressin – used to reduce urine production.
- Digoxin – used to treat heart problems. Your doctor may add sufficient amounts of potassium as a lack of potassium may develop if this medicine is used in large volumes.

- Insulin – used to treat high blood sugar (diabetes).
- Lithium - used to treat mood swings and some forms of depression.
- Medicines used to treat asthma and to open the lungs, called beta-2 agonists.
- Medicines used to treat certain types of cancer (e.g., vincristine, ifosfamide, cyclophosphamide).
- Medicines used to treat depression, called selective serotonin reuptake inhibitors (SSRIs).
- Medicines used to treat epilepsy (e.g., carbamazepine, oxcarbazepine).
- Medicines used to treat certain mental conditions, called antipsychotics.
- Medicines used to treat severe pain, called narcotics.
- Medicines used to treat pain and inflammation, called nonsteroidal anti-inflammatory drugs (NSAIDs).
- Medicines used to pass more urine, called diuretics.
- Oxytocin – used in childbirth.
- Terlipressin – used to treat low blood pressure.

Ask your doctor, pharmacist, or other healthcare provider if you are not sure about your medicine.

Your doctor or other healthcare provider will ensure that blood is not given to you through the same intravenous set, as this may result in blood clotting.

### **Pregnancy and breastfeeding**

Safety during pregnancy and breastfeeding has not been established.

The administration of SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS during labour may result in abnormally high or low blood glucose levels or an acid-base imbalance in the fetus.

Your doctor will administer SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS with special caution during labour especially if he/she is also giving you oxytocin, due to the risk of low blood sodium levels.

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 SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS.

### **Driving and using machines**

After receiving SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS your ability to drive and use machines should not be compromised. However, do take care until you know how SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS infusion affects you. Your doctor will decide when you can be discharged from the hospital or clinic.

It is not always possible to predict to what extent SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above-mentioned activities until they are aware of the measure to which SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS affects them.

### **SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS contains sodium**

SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS contains 3,54 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0,18 % of the recommended maximum daily dietary intake of sodium for an adult.

### **3. How to receive SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS**

You will not be expected to give yourself SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS. It will be given to you by a person who is qualified to do so.

SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % 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 laboratory results.

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

**If you receive more SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS than you should**

Since a healthcare provider will administer SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

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

**If you forget to receive SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS**

Since a healthcare provider will administer SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS, it is unlikely that the dose will be missed.

**4. Possible side effects**

SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS can have side effects. Not all side effects reported for SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS, please consult your healthcare provider for advice.

**If any of the following happens, stop receiving SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS and tell your doctor 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.
- Too little sodium in your blood causing mental confusion, irreversible brain injury and/or death.

These are all very serious side effects. If you have them, you may have had a serious reaction to SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS. You may need urgent medical attention or further hospitalisation.

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

- Swelling from too much fluid in your body.
- Abnormally high blood sugar levels.
- Too much sodium in your blood.
- Too much chloride in your blood causing your blood to become acidic.
- Fever, chills.
- Irritation or inflammation of a vein.
- Infection at site of injection.
- Pain, irritation, rash, itching or redness of the skin surrounding the injection site.

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](mailto: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 via the **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 SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS.

### **5. How to store SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS**

Store at or below 25 °C.

Use immediately after the bag is opened.

Discard after single use.

Discard any unused portion.

Store all medicines out of reach of children.

### **6. Contents of the pack and other information**

#### **What SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS contains**

The active substances are sodium chloride and dextrose anhydrous or dextrose monohydrate.

Each 1 000 ml contains:

Sodium chloride	9,0 g
Dextrose anhydrous	50,0 g
or Dextrose monohydrate	55,0 g

*Providing:*

Sodium ions: 154 mmol/l

Chloride ions: 154 mmol/l

The other ingredient is water for injection.

Contains sugar: Dextrose (glucose). Each ml contains 50 mg dextrose anhydrous or 55 mg dextrose monohydrate.

**What SODIUM CHLORIDE 0,9 % WITH DEXTROSE 5 % FRESENIUS looks like and contents of the pack**

Clear, colourless, or faintly straw-coloured solution.

SODIUM CHLORIDE 0.9 % WITH DEXTROSE 5 % FRESENIUS, Solution for Infusion is filled into 200 ml, 500 ml or 1 000 ml *freeflex*® or PVC bags.

Each bag is labelled and over pouched. The *freeflex*® bags are overwrapped with a multilayer foil and the PVC bags are over pouched with a nylon/polypropylene film or an HDPE over pouch film. The overwrapped *freeflex*® or PVC bags are packed into corrugated cardboard shipper boxes.

*Pack sizes per corrugated cardboard shipper box.:*

- 30 or 40 x 200 ml filled in 250 ml *freeflex*® or 200 ml PVC bags.
- 30 x 500 ml *freeflex*® bags.
- 12 x 1 000 ml *freeflex*® or PVC bags.

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

**Holder of Certificate of Registration**

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten 6020

Gqeberha

South Africa

Tel.: +27 (0)41 403 1600

**This leaflet was last revised in**

04 August 2022

**Registration number**

D/24/155