

Approved Patient Information Leaflet for Sodium Chloride 5 % Fresenius

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

SODIUM CHLORIDE 5 % FRESENIUS solution for infusion

Sodium chloride

Sugar free

Read all of this leaflet carefully before you are given SODIUM CHLORIDE 5 % FRESENIUS

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

What is in this leaflet

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

1. What SODIUM CHLORIDE 5 % FRESENIUS is and what it is used for

SODIUM CHLORIDE 5 % FRESENIUS is a hypertonic solution that is used for severe sodium deficits.

2. What you need to know before you are given SODIUM CHLORIDE 5 %

FRESENIUS

SODIUM CHLORIDE 5 % FRESENIUS should not be given:

- to you if you are hypersensitive (allergic) to SODIUM CHLORIDE 5 % FRESENIUS
- to babies, young children and the elderly if undiluted.

Warnings and precautions

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

Special care should be taken with SODIUM CHLORIDE 5 % FRESENIUS:

- if SODIUM CHLORIDE 5 % FRESENIUS is given to children, as they may have impaired ability to regulate fluids and electrolytes
- if SODIUM CHLORIDE 5 % FRESENIUS is given to the elderly, as they may have decreased liver, kidney or heart function, have other diseases or be on other medicines
- if you have primary or secondary hyperaldosteronism, a condition where your body creates too much of the hormone aldosterone, resulting in too much sodium and fluid in the blood
- if you have high blood pressure or congestive heart failure (inability of the heart to supply sufficient blood flow)
- if you are pregnant and have high blood pressure
- if you have liver disease or liver damage
- if you have severely impaired kidney function or kidney damage
- if you have a condition that causes water retention (swelling) or water on the lungs
- if you are taking medicines that may increase the risk of sodium and fluid retention, such as corticosteroids or corticotrophin.

Children and adolescents

Your healthcare provider will closely monitor blood concentrations in children, as children may have an impaired ability to regulate fluids and electrolytes.

The elderly

When selecting the appropriate medicine for an older person, your healthcare provider will consider that older people are generally more likely to have reduced liver, kidney or heart function and have other diseases or use other medicines.

Other medicines and SODIUM CHLORIDE 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:

- Corticosteroids - used to treat rheumatoid arthritis, inflammatory bowel disease (IBD), asthma, allergies and other conditions.
- Corticotrophin – used to treat certain types of hormone deficiency.
- Lithium – used to treat mood swings and some forms of depression. Administration of SODIUM CHLORIDE 5 % FRESENIUS may result in decreased lithium levels.

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

Pregnancy and breastfeeding

Safety during 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 SODIUM CHLORIDE 5 % FRESENIUS.

Driving and using machines

Since side effects related to dehydration, such as dizziness, drowsiness, confusion, convulsions and coma have been reported in patients receiving SODIUM CHLORIDE 5 % FRESENIUS, patients should not drive, use machinery or perform any tasks that require concentration, until they are certain that SODIUM CHLORIDE 5 % FRESENIUS does not adversely affect their ability to do so.

3. How to receive SODIUM CHLORIDE 5 % FRESENIUS

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

Dose:

SODIUM CHLORIDE 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.

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

Your healthcare provider will always inspect containers for intactness of seals and the solutions for injection for discolouration or presence of any visible particulate matter. 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.

If you receive more SODIUM CHLORIDE 5 % FRESENIUS than you should

Since a healthcare provider will administer SODIUM CHLORIDE 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 provider or pharmacist for more information.

If you forget to receive SODIUM CHLORIDE 5 % FRESENIUS

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

4. Possible side effects

SODIUM CHLORIDE 5 % FRESENIUS can have side effects.

Not all side effects reported for SODIUM CHLORIDE 5 % FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving SODIUM CHLORIDE 5 % FRESENIUS, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop receiving SODIUM CHLORIDE 5 % FRESENIUS and tell your doctor immediately:

- Hypersensitivity reactions such as a fast heartbeat, chest pain, difficulty in breathing and flushing.
- Convulsions from too much salt in the blood.
- Too high salt concentration in the blood from unsuitable intravenous use of SODIUM CHLORIDE 5 % FRESENIUS. This may lead to a serious side effect where the brain loses water, resulting in sleepiness, confusion, convulsions, coma, respiratory failure and death.

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

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

- Thirst.
- Less saliva and tear formation.
- Fever.
- Sweating.
- Abnormal rapid beating of the heart.
- High blood pressure or low blood pressure.
- Headache.
- Dizziness.
- Restlessness, irritability.
- Weakness.
- Muscular twitching and rigidity (stiffness and resistance to movement).

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

Tell your doctor if you notice any of the following:

- Hives, rash and itching.
- Shaking or quivering.
- Chills.
- Too much fluid on the lungs.
- Abnormal electrolyte levels in the body.
- Injection site reactions such as infection, irritation, redness, hives and a burning sensation.
- Vein irritation.
- Vein inflammation with clot formation.
- Swelling.

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 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 5 % FRESENIUS.

5. How to store SODIUM CHLORIDE 5 % FRESENIUS

Store at or below 25 °C.

Use immediately after the bag is opened.

Discard any unused portion.

Store all medicines out of reach of children.

6. Contents of the pack and other information

The active ingredient is sodium chloride.

Each 200 ml contains 10 g sodium chloride.

The other ingredient is water for injection.

Sugar free.

What SODIUM CHLORIDE 5 % FRESENIUS looks like and contents of the pack:

A clear, colourless solution in 200 ml freeflex (polyolefine) or PVC bags packed into cardboard shipper boxes in pack sizes of 30 or 40.

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

Holder of Certificate of Registration and Manufacturer:

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten 6020

Gqeberha

South Africa

Tel: +27 (0)41 403 1600

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