APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

SODIUM CHLORIDE 0,9 % FRESENIUS

Sodium Chloride

Sugar free

Read all of this leaflet carefully before you are given SODIUM CHLORIDE 0,9 % 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 % FRESENIUS is and what it is used for

This medicine contains sodium chloride at a concentration similar to the concentration of salts in your blood.

It is used to replace fluids lost from your body such as when you are dehydrated or to prevent

dehydration.

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

SODIUM CHLORIDE 0,9 % FRESENIUS should not be administered to you:

- if you are hypersensitive (allergic) to sodium chloride or any of the other ingredients of SODIUM CHLORIDE 0,9 % FRESENIUS (listed in section 6).

Warnings and precautions

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

- heart disease or heart failure
- impaired kidney function
- acidification of the blood (acidosis)
- liver disease (e.g. cirrhosis)
- when there is a larger volume of blood in the blood vessels than there should be (hypervolaemia)
- high blood pressure (hypertension)
- pre-eclampsia (high blood pressure during pregnancy)
- fluid retention resulting in swelling of parts of the body, particularly your feet and ankles (peripheral oedema) or build-up of fluid in the lungs (pulmonary oedema).
- any other condition associated with sodium retention (when the body retains too much sodium), such as treatment with steroids (see also below “Other medicines and SODIUM CHLORIDE 0,9 % FRESENIUS”)
- raised production of the hormone aldosterone (aldosteronism)
- if you have a condition that could cause high levels of vasopressin, a hormone regulating fluid in your body. You may have too much vasopressin in your body because, for example:

- you have had a sudden and serious illness
- you are in pain
- you have had surgery
- you have infections, burns or brain disease
- you have diseases linked to your heart, liver, kidneys or central nervous system
- because you are taking certain medicines (see also below "Other medicines and SODIUM CHLORIDE 0,9 % FRESENIUS")

This may increase the risk of low levels of sodium in your blood and can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain and death.

Brain swelling increases the risk of death and brain damage. People who are at higher risk of brain swelling are:

- children
- women (particularly if you are of a fertile age)
- people who have problems with their brain fluid levels, for example, because of meningitis, bleeding in the skull or a brain injury

Other medicines and SODIUM CHLORIDE 0,9 % FRESENIUS

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

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

- corticosteroids (anti-inflammatory medicines). These medicines can cause the body to accumulate sodium and water, leading to tissue swelling due to fluid collection under the skin (oedema) and high blood pressure (hypertension).
- lithium (used to treat psychiatric illness).
- Some medicines act on the hormone vasopressin. These may include:
  - anti-diabetic medication (chlorpropamide)

- cholesterol medicine (clofibrate)
- some cancer drugs (vincristine, ifosfamide, cyclophosphamide)
- selective serotonin reuptake inhibitors (used to treat depression)
- antipsychotics
- opioids for severe pain relief
- medicines for pain and/or inflammation (also known as NSAIDs)
- medicines that imitate or strengthen the effects of vasopressin such as desmopressin (used to treat increased thirst and urination), terlipressin (used to treat bleeding of the gullet) and oxytocin (used to induce labour)
- anti-epileptic medication (carbamazepine and oxcarbazepine)
- diuretics (water tablets)

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 healthcare provider for advice before using this medicine.

Pregnancy

SODIUM CHLORIDE 0,9 % FRESENIUS can be used as indicated.

Special care will be taken if you have a specific disorder that may occur during pregnancy, called eclampsia, with the following symptoms: high blood pressure, cramps, swelling.

Breastfeeding

As the concentration of sodium and chloride are similar to that in human body no harmful effects are to be expected if the product is used as indicated.

SODIUM CHLORIDE 0,9 % FRESENIUS can be used during breastfeeding, if required.

Driving and using machines

SODIUM CHLORIDE 0,9 % FRESENIUS does not influence your ability to drive and use machines.

SODIUM CHLORIDE 0,9 % FRESENIUS contains sodium

Electrolyte concentrations:

Sodium: 154 mmol/L

Chloride: 154 mmol/L

3. How to use SODIUM CHLORIDE 0,9 % FRESENIUS

Do not share medicines prescribed for you with any other person.

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

Your doctor will decide the correct dosage for you and how and when the injection will be given. Your doctor will tell you how long your treatment with SODIUM CHLORIDE 0,9 % FRESENIUS will last.

If you have the impression that the effect of SODIUM CHLORIDE 0,9 % FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

If you are given more SODIUM CHLORIDE 0,9 % FRESENIUS than you should

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

If you think you have been given too much, and you start feeling thirsty, confused, weak, and drowsy or have a headache or fast heartbeat, you must tell the person giving you the injection.

4. Possible side effects

SODIUM CHLORIDE 0,9 % FRESENIUS can have side effects.

Not all side effects reported for SODIUM CHLORIDE 0,9 % FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using SODIUM CHLORIDE 0,9 % FRESENIUS, please consult your healthcare provider for advice.

Tell your healthcare provider immediately if you start having fits or a headache, or start feeling nauseas, weak or confused.

Not known: frequency cannot be estimated from the available data

- tremor
- decreased blood pressure
- local pain or reaction (redness or swelling at the site of infusion)
- infection at the site of infusion
- itching (pruritus) at the site of infusion
- hives (urticaria), skin rash
- irritation and inflammation of the vein into which the solution is infused (phlebitis).

  This can cause redness, pain or burning and swelling along the path of the vein into which the solution is infused.
- the formation of a blood clot (venous thrombosis) at the site of infusion, which causes pain, swelling or redness in the area of the clot
- escape of the infusion solution into the tissues around the vein (extravasation).

  This can damage the tissues and cause scarring.
- an excess of fluid in the blood vessels (hypervolaemia)

- fever
- chills
- low levels of sodium in the blood that may be acquired during hospitalization (nosocomial hyponatraemia) and related neurological disorder (acute hyponatraemic encephalopathy). Hyponatraemia can lead to irreversible brain injury and death due to (cerebral oedema/swelling) (see also in the section 2 “Warning and precautions”)

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SODIUM CHLORIDE 0,9 % FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or 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 SODIUM CHLORIDE 0,9 % FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 ºC.

Do not use this medicine after the expiry date which is stated on the labels. The expiry date refers to the last day of that month.

Do not use SODIUM CHLORIDE 0,9 % FRESENIUS if you notice that the solution appears

cloudy or coloured, if you find particles in the solution or if the container is leaking. This medicine is for single use only. After use, container and any remaining contents have to be discarded.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SODIUM CHLORIDE 0,9 % FRESENIUS contains

The active substance is sodium chloride.

The other ingredients are water for injection, hydrochloric acid (pH adjustment) and sodium hydroxide (pH adjustment).

What SODIUM CHLORIDE 0,9 % FRESENIUS looks like and contents of the pack

Clear, colourless, sterile solution

SODIUM CHLORIDE 0,9 % FRESENIUS is packed in:

1 or 50 or 60 x 50 mL *free***flex** (non-PVC) bags

1 or 40 or 50 x 100 mL flexible *free***flex** (non-PVC)

1 or 30 or 40 x 200 mL flexible *free***flex** (non-PVC)

1 or 18 or 20 x 500 mL flexible *free***flex** (non-PVC)

1 or 12 x 1 000 mL flexible *free***flex** (non-PVC)

500 ml and 1 000 mL polyethylene bottles

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten 6020

Gqeberha

South Africa

Telephone: +27 (0)86 0203 900

This leaflet was last revised on

28 August 2025

Registration Number

C/24/219

Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.

Botswana:	BOT1702928E/F/G/J [S2]
Namibia:	[NS2] 90/24/00446
Zimbabwe:	2003/23.2.1/4187, PP
	23.2.1 Parenteral (Large volume infusions)