Approved Professional Information for Sodium Chloride 5 % Fresenius

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

SODIUM CHLORIDE 5 % FRESENIUS solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 200 ml contains 10 g sodium chloride.

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion.

A clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Solution of SODIUM CHLORIDE 5 % FRESENIUS is used to correct severe sodium deficits.

4.2 Posology and method of administration

Posology

Use only when the solution is clear and container seals are intact.

As directed by a medical doctor. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations.

Serum-electrolyte concentration should be carefully monitored.

When physiological conditions are re-established, dosage must be reduced.

Method of administration

Intravenous infusion.

4.3 Contraindications

Undiluted SODIUM CHLORIDE 5 % FRESENIUS should not be administered intravenously to neonates, young children and the elderly (see section 4.4).

4.4 Special warnings and precautions for use

Hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus may occur with SODIUM CHLORIDE 5 % FRESENIUS.
Stop the infusion immediately if signs or symptoms of a hypersensitivity reaction develop, such as tachycardia, chest pain, dyspnoea and flushing. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Depending on the volume and rate of infusion, the intravenous administration of SODIUM CHLORIDE 5 % FRESENIUS can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration/hypervolaemia, congested states, pulmonary oedema, or acid-base imbalance. The risk of dilutive states is inversely proportional to the electrolyte concentration of the injection. The risk of solute overload causing congested states with peripheral and pulmonary oedema is directly proportional to the electrolyte concentrations of the injection.

Monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

SODIUM CHLORIDE 5 % FRESENIUS should be used with great care in patients with or at risk for hypernatraemia, hyperchloraemia, hypervolaemia or with conditions that may cause sodium retention, fluid overload and oedema, such as patients with primary or secondary hyperaldosteronism, hypertension, peripheral or pulmonary oedema, congestive heart failure, liver disease including cirrhosis, severe renal insufficiency including renal artery stenosis and nephrosclerosis, pre-eclampsia and in clinical states in which there exists oedema with sodium retention.
Certain medicines may increase the risk of sodium and fluid retention (see section 4.5).
In patients with diminished renal function, administration of SODIUM CHLORIDE 5 % FRESENIUS may result in sodium retention.

SODIUM CHLORIDE 5 % FRESENIUS is hypertonic with an osmolarity of 1 710 mOsm/l (approx.) and may cause vein damage and thus should be administered through a large vein, for rapid dilution.

Do not mix or administer SODIUM CHLORIDE 5 % FRESENIUS solutions through the same administration set with whole blood or cellular blood components.

Rapid correction of hypo- and hypernatraemia is potentially dangerous (risk of serious neurologic complications). Dosage, rate, and duration of administration should be determined by a doctor experienced in intravenous fluid therapy.

Paediatric population

Plasma electrolyte concentrations should be closely monitored in the paediatric population as this population may have impaired ability to regulate fluids and electrolytes.

Geriatric population

Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other medicine therapy.

SODIUM CHLORIDE 5 % FRESENIUS is substantially excreted by the kidney, and the risk of toxic reactions to this medicine may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

4.5 Interaction with other medicines and other forms of interaction

Caution must be exercised in the administration of SODIUM CHLORIDE 5 % FRESENIUS to patients receiving medicines that may increase the risk of sodium and fluid retention, such as corticosteroids or corticotrophin.

Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be increased during the administration of SODIUM CHLORIDE 5 % FRESENIUS. Administration of SODIUM CHLORIDE 5 % FRESENIUS may, therefore, result in decreased lithium levels.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

Since adverse reactions related to dehydration, such as dizziness, somnolence, 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 (see sections 4.4, 4.8).

4.8 Undesirable effects

a) Summary of the safety profile

Convulsions can result from iatrogenically induced hypernatraemia.

Hypernatraemia may also occur after inappropriate intravenous use of SODIUM CHLORIDE 5 % FRESENIUS.

The most serious effect of hypernatraemia is dehydration of the brain which causes somnolence and confusion progressing to convulsions, coma, respiratory failure, and death.

b) Tabulated summary of adverse reactions

System organ class	**Adverse reaction** **Frequency unknown** (cannot be estimated from the available data)
Metabolism and nutrition disorders	Overhydration/hypervolaemia* Hyperchloraemia Hyperchloraemic metabolic acidosis Acid-base imbalance Thirst Reduced salivation
Nervous system disorders	Dehydration of the brain Somnolence Confusion Convulsions Coma Headache Dizziness

	Restlessness Irritability
Eye disorders	Reduced lachrymation
Cardiac disorders	Tachycardia Hypertension Hypotension
Vascular disorders	Peripheral oedema Venous thrombosis extending from the site of injection* Phlebitis extending from the site of injection*
Respiratory, thoracic and mediastinal disorders	Respiratory failure Pulmonary oedema
Skin and subcutaneous tissue disorders	Urticaria Rash Pruritis
Musculoskeletal and connective tissue disorders	Muscular twitching Rigidity
General disorders and administrative site conditions	Fever Tremor Chills Sweating Weakness Febrile response* Injection site infection* Injection site irritation* Injection site erythema*

	Injection site streaking* Injection site urticaria* Burning sensation* Extravasation*

*Adverse reactions which may occur because of SODIUM CHLORIDE 5 % FRESENIUS or the technique of administration.

c) Description of selected adverse reactions

Hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus may occur with SODIUM CHLORIDE 5 % FRESENIUS.

Stop the infusion immediately if signs or symptoms of a hypersensitivity reaction develop, such as tachycardia, chest pain, dyspnoea and flushing. Appropriate therapeutic countermeasures must be instituted as clinically indicated (see section 4.4).

d) Paediatric population

Plasma electrolyte concentrations should be closely monitored in the paediatric population as this population may have impaired ability to regulate fluids and electrolytes (see section 4.4).

e) Other special populations

SODIUM CHLORIDE 5 % FRESENIUS is substantially excreted by the kidney, and the risk of toxic reactions to this medicine may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function (see section 4.4).

Reporting of suspected adverse reactions

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.

Reporting suspected adverse reactions after authorisation of SODIUM CHLORIDE 5 % FRESENIUS is important. It allows continued monitoring of the benefit/risk balance of SODIUM CHLORIDE 5 % FRESENIUS. Health care providers are asked to report any suspected adverse reactions via the **Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Excessive administration of SODIUM CHLORIDE 5 % FRESENIUS may lead to hypernatraemia (which can lead to CNS manifestations, including seizures, coma, cerebral oedema and death) and sodium overload (which can lead to central and/or peripheral oedema).

When assessing an overdose, any additives in the solution must also be considered. The effects of an overdose may require immediate medical attention and treatment.

In cases of patients unable to retain the sodium selectively the treatment must be discontinued.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 24 Mineral substitutes, electrolyte.

Pharmacotherapeutic group: Electrolyte solutions.

ATC code: B05XA03.

Mechanism of action

5 % sodium chloride is a hypertonic solution and is necessary for the replacement of severe sodium deficits.

5.2 Pharmacokinetic properties

Sodium chloride is well absorbed from the gastrointestinal tract. Excess sodium is mainly excreted by the kidney, and small amounts are lost in the faeces and sweat.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection

Osmolarity: 1 710 mOsm/l

pH: 6,0

Constituents: Sodium ions: 855 mmol/l

Chloride ions: 855 mmol/l

6.2 Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines.

6.3 Shelf life

Freeflex (polyolefine) and PVC bags:

24 months

In-use shelf-life:

To be used immediately after the bag is opened.

6.4 Special precautions for storage

Store at or below 25 °C.

Discard any unused portion.

For storage of the opened product, see section 6.3.

6.5 Nature and contents of container

200 ml solution in 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.

6.6 Special precautions for disposal and other handling

Discard any unused portion.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten 6020

Gqeberha

South Africa

8. REGISTRATION NUMBER

L/24/229

9. DATE OF FIRST AUTHORISATION

03 January 1979

10. DATE OF REVISION OF THE TEXT

20 May 2022