APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS Diluent for Injection

2. QUALITATIVE AND QUANTITIVE COMPOSITION

Each 10 ml contains 0,09 g sodium chloride.

Each ml of solution contains 9 mg of sodium chloride.

Osmolarity: 308 mOsmol/L.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solvent for parenteral use.

Clear and colourless solution, free or practically free from particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS is for use as a diluent for reconstitution of a compatible medicinal product.

4.2 Posology and method of administration

Posology

SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS is intended for use as a diluent for reconstitution of a compatible medicinal product.

The amount to be used will depend on the concentration wanted for the administration of the medicine to be dissolved.

Method of administration

Intravenous, intramuscular or subcutaneous use.

4.3 Contraindications

Intravenously, SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS should be administered cautiously to young children and elderly patients.

Due to the indications of the product, contraindications depend on the medicine to be dissolved.

In general, the administration of this product is contraindicated in the following situations:

- Hypernatraemia
- Hypertonia
- Cardiac insufficiency
- Oedematous states in patients with cardiac, hepatic or renal disorders
- Severe hypertension
- Metabolic acidosis.

4.4 Special warnings and precautions for use

See section 4.3.

Once the container is opened the solution should be used immediately.

In case of subcutaneous administration, no supplement should be added, since isotonicity would change.

Do not use the solution if it is not clear or have visible precipitates.

Before adding the medicine to the SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS ampoule compatibility between the substance to be administered and sodium chloride should be checked.

Sodium chloride should be used with precaution in patients with hypertension, cardiac failure, pulmonary or peripheral oedema, renal impairment, pre-eclampsia, hyperaldosteronism, cirrhosis and other disorders of liver, hypervolaemia, urinary tract obstruction, hypoproteinaemia and other sicknesses and treatments (e.g., corticosteroids) associated to sodium retention.

Paediatric population

Newborns, whether premature or not, can present too high sodium levels due to immaturity of renal function. Therefore, in newborns, whether premature or not, repeated injections of sodium chloride can only be administered after sodium levels in the blood have been determined.

4.5 Interaction with other medicines and other forms of interactions

Interactions depend on the medicine to be dissolved.

Sodium chloride is incompatible with lithium carbonate, whose renal excretion is directly proportional to the sodium levels in the body. Administration of

sodium chloride accelerates renal excretion of lithium, causing a decrease of its therapeutical action.

The addition of alcohol to sodium chloride solutions should be avoided.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/ Contraception in males and females

No information available.

Pregnancy

Safety in pregnancy has not been established; therefore, it is recommended to be used with precaution if it is administered during pregnancy.

Breastfeeding

Safety in lactation has not been established; therefore, it is recommended to be used with precaution if it is administered during lactation.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Convulsions may result from iatrogenically induced hypernatraemia.

General disorders and administration site conditions may be provoked.

Inadequate or excessive administration of physiologic saline solution may produce hyperhydration, hypernatraemia, hyperchloraemia and related signs such as metabolic acidosis because of decrease of bicarbonate concentration and oedema formation.

An excess of sodium chloride may produce nausea, vomiting and headache.

As SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS solvent for parenteral use is used as a diluent of injectable preparations, the nature of the product added determine the probability of appearance of undesirable effects.

In case of adverse reactions due to the associated medicine, infusion should be immediately discontinued, the patient should be evaluated, suitable corrective measures should be established, and the solution should be kept for a later analysis should it become necessary.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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.

4.9 Overdose

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

An excess of sodium chloride, in its most acute form, produces dehydration of internal organs, nausea, vomiting, diarrhoea, abdominal cramps, thirst, decrease of salivation, water, sweat, fever, hypotension, tachycardia, renal

failure, pulmonary oedema, acidosis, respiratory insufficiency, headache, vertigo, irritability, muscle spasms, rigidity, coma and death.

Due to the nature of the product, if its indication and administration are correct and controlled there is no risk of intoxication.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 24 Mineral substitutes, electrolytes

Pharmacotherapeutic group: Solvent and diluent agents including solutions for irrigation, ATC code: V07AB.

Sodium chloride plays a physiological role in the maintenance or replacement of fluids and electrolyte imbalances or deficits in extracellular fluid. Sodium chloride 0,9 % solution is an isotonic solution.

5.2 Pharmacokinetic properties

Absorption

Due to the intravenous administration of the product, there will not be any absorption.

Distribution

Sodium and chloride electrolytes are distributed, mainly in extracellular fluid. As physiologic saline solution is isotonic the administration of this solution will not provoke any change in osmotic pressure of extracellular fluid, so there will not be any circulation of water to intracellular compartment and both ions will not practically penetrate in the cell.

Nevertheless, a decrease (for dilution) on oncotic pressure of plasmatic proteins will be produced, and this will provoke the circulation of water to interstitial compartment through capillary walls, and normality could be reached.

It should be considered that the richest tissue in water is muscles, whilst sodium is mainly found in bounds, constituting one of the main reserves of bones.

Elimination

Sodium ion is mainly eliminated through the kidneys (95 %) and the rest through the skin (sweat) and digestive system.

Water is eliminated through the kidneys, skin, lungs and digestive system. Therefore, the kidney is the most important organ in the maintenance of concentration of extracellular sodium. The amount being excreted of this cation will depend on the needs of the body.

Urine with concentrations lower that 1 mmol sodium/L could even be produced.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

Hydrochloric acid (for pH adjustment) or sodium hydroxide (for pH adjustment).

6.2 Incompatibilities

Before adding a medicine, the compatibility between the added products should be checked.

SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS is incompatible with hydrocortisone, amphotericin B, tetracyclines, cephalothin, erythromycin, lactobionate and lithium salts.

It is also incompatible with active ingredients that are not soluble in the sodium chloride solution, because of an eventual precipitation of the active ingredient.

It is also incompatible with medicines for which a very acid or very alkaline pH is necessary for their stability or solubility.

6.3 Shelf life

Shelf life of the product: 2 years

Shelf life after first opening: immediate use

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

Low-density polyethylene (LDPE) ampoules.

10 ml ampoules of low-density polyethylene ampoules containing 0,9 % sodium chloride in packs of 20 and 50 ampoules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

It is not necessary to sterilise the bottle before its opening.

It is not necessary to use any cutting element to open the ampoule.

Once the ampoule is opened the top of it can perfectly be adjusted to the syringe cone (cone Luer), with which it is necessary to use the needle.

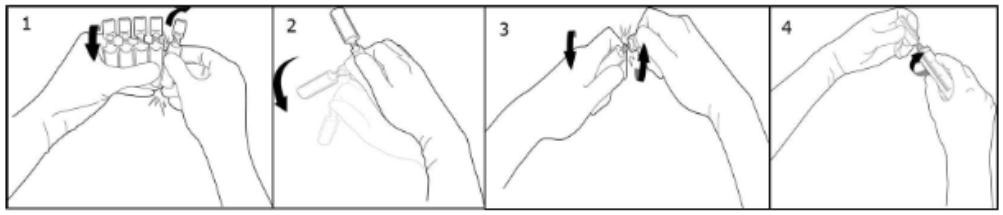
Handling instructions

To break off a single ampoule, twist one ampoule against the remaining ampoules of the pack without touching the head and neck of the ampoules (1).

Shake the ampoule with one single movement as shown below in order to remove the liquid kept in the cap (2).

To open the ampoule, twist the ampoule body and the ampoule head in opposite directions until the neck breaks off (3).

Connect the ampoule to the Luer-syringe or Luer-lock syringe as shown in figure (4).



Therefore, no needle is needed to extract the solution. Extract the liquid.

The solution does not contain any type of preservative or bactericide, therefore opened ampoules and any unused solution should be discarded immediately.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Fresenius Kabi South Africa (Pty) Ltd

Stand 7, Growthpoint Business Park

2 Tonetti Street, Halfway House, Extension 7

Midrand, 1685

South Africa

Telephone number: +27 (0)11 545 0000

8. REGISTRATION NUMBER

L/24/166

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

30 January 1979

10. DATE OF REVISION OF THE TEXT

10 February 2025.