APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S1**

SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS

Sodium chloride

Diluent for solution for injection

Sugar free

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

For use as a diluent for reconstitution of a compatible medicinal product.

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

SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS should not be administered to you if you are suffering from:

- Higher levels of sodium in the blood than normal (hypernatraemia).
- If you have an increase of muscle tone (hypertonia).
- If you suffer from cardiac insufficiency (incapability of the heart to pump the necessary, amount of blood).
- If you have some heart, liver or kidney disorder and if you suffer from an accumulation of water (oedema) in your body.
- If you have a severe high blood pressure (severe hypertension).
- If you have an excess of acidity in your blood (metabolic acidosis).

Warnings and precautions

Special care should be taken with SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS:

Talk to your doctor or nurse before using SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS.

- Once opened the solutions should be used immediately.
- In case of subcutaneous administration your healthcare provider will not add any supplement, since isotonicity would change.
- Your healthcare provider will not use the solution if it is not transparent or has precipitates.

- Your healthcare provider will make sure about the physical-chemical compatibility when adding any medicine to the ampoule.

Tell your doctor if you have:

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.

Children

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

Newborns can present too high sodium levels due to immaturity of renal function. Therefore, repeated injections of sodium chloride can only be administered after sodium levels in the blood have been determined.

Other medicines and SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS

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

Interactions with other medicines depend on the medicine to be added to SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS.

SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS solution presents incompatibilities with lithium salts.

Your healthcare provider will consider that addition of alcohol to SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS solution should be avoided.

SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS with food and drink

You should ask your doctor about what you can eat or drink.

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 receiving SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS.

Driving and using machines

Ask your doctor or nurse for advice before driving or using machines.

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

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

For use as a diluent for reconstitution of a compatible medicinal product.

You will not be expected to give yourself the solution containing SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS. The solution will be given to you by a person who is qualified to do so.

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

The medicine dissolved in SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS will be administered intravenously, intramuscularly or subcutaneously, depending on the nature and volume of the medicine to be administered.

If you receive more SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS than you should

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

If you forget to use SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS

Since a healthcare provider will administer the solution containing SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS, it is unlikely that the dose will be missed.

Stop receiving SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS solution.

Your doctor will decide when to stop giving you the medicine.

4. POSSIBLE SIDE EFFECTS

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

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

Tell your doctor if you notice any of the following

Convulsions.

Nausea, vomiting and headache. This may be due to an excess of sodium chloride.

Too little or too much physiologic saline solution can produce hyperhydration (water poisoning), hypernatraemia (high concentration of sodium in blood), hyperchloraemia (excess of chloride ions in blood) and related signs such as metabolic acidosis (too many acids in blood, because of decrease of bicarbonate concentration) and oedema (swelling).

Side effects can also be related to the added medicine.

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 % FLEXIVIAL 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 % FLEXIVIAL FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not use SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS after the expiry date which is stated on the container after EXP. The expiry date refers to the last day of that month.

SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS will be stored and handled appropriately by your healthcare provider.

6. Contents of the pack and other information

What SODIUM CHLORIDE 0,9 % FLEXIVIAL FRESENIUS contains:

- The active substance is sodium chloride: Each 10 ml contains 0,09 g sodium chloride.
- The other ingredients are water for injections, hydrochloric acid or sodium hydroxide for pH adjustment.

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

Clear, colourless, sterile solution of sodium chloride in water for injection, practically free from particles.

10 mL ampoules in packs of 20 and 50 ampoules

Not all pack sizes may be marketed.

Holder of the Certificate of Registration

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