Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.9 % w/v solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium chloride: 9 g/l
Each ml contains 9 mg sodium chloride.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.
Clear and non coloured solution**.**
Sodium:.....154 mmol/l
Chloride:.....154 mmol/l
Osmolality:..... 290 mosmol/kg
Osmolarity:..... 308 mosmol/l

pH between 4.5 and 7.0.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicine is indicated in the following situations:
- Treatment of sodium depletion.
- Treatment of isotonic extracellular dehydration.
- Treatment of hypovolaemia.
- Vehicle or diluent of compatible drugs for parenteral administration of medicines.

4.2 Posology and method of administration

By intravenous infusion using sterile equipment and aseptic method.
1 g of sodium chloride corresponds to 394 mg or 17.1 mEq or17.1 mmolof sodium ion.
The recommended dosage for treatment of isotonic extracellular dehydration and sodium depletion is:
- **for adults :** 500 ml to 3 Liters/24 h
- **for babies and children :** 20 to 100 ml per 24 h and per kg of body weight, depending of the age and the total body mass.

The infusion rate depends on the patient's clinical condition.
The recommended dosage when used as a vehicle or diluent ranges from 50 to 250 ml per dose of medicinal product to be administered.
When Sodium Chloride 0.9 %, solution for infusion, is used as a diluent for injectable preparations of other drugs, the dosage and the infusion rate will be principally dictated by the nature and the dose regimen of the prescribed drug.

4.3 Contraindications

This medicine should not be administrated in case of water/sodium retention situations, and in particular:

- decompensated heart failure
- acute renal failure with oliguria or anuria.

Furthermore, when isotonic Sodium Chloride 0.9 %, solution for infusion, is used as a vehicle, contraindication related to the added medicinal product(s) should be considered.

4.4 Special warnings and precautions for use

Special warnings:

- Check that the container is undamaged and that the solution is clear before use.
- Discard any damaged or partially used container.
- Use in aseptic conditions.

Sodium Chloride 0.9 %, solution for infusion,must be used with caution in patients with hypertension, heart failure, hepatocellular insufficiency with oedema and ascitis, peripheral or pulmonary oedema, impaired renal function, pre-eclampsia, aldosteronism, or other conditions and treatment associated with sodium retention.

Precautions for use:
Administration should be carried out under regular and careful surveillance.
Clinical and biological parameters, in particular serum-electrolytes, should be monitored..
Premature or term infants may retain an excess of sodium due to immature renal function. In premature or term infants, repeated infusions of sodium chloride should therefore only be given after determination of the serum sodium level.

- The physician should judge the incompatibility of an additive drug with the Sodium Chloride 0.9 %, solution for infusion,by checking for any possible change in colour and/or possible formation of precipitate, insoluble complex or crystals.
- Before adding any drug, check that the pH range in which it is effective is the same as that of 0.9% sodium chloride solution (pH = 4.5 – 7.0).
- Please refer to the drug's package insert.
- When any drug is added to the Sodium Chloride 0.9 %, solution for infusion, the mixture must be administered immediately.

Precautions for using bag :

- do not use an air entry;
- flush the infusion system in order to avoid any passage of air.
- do not connect in series since the residual of the first container might be carried on by the solution coming from the second container, with the risk of air embolism.

4.5 Interaction with other medicinal products and other forms of interaction

See section 4.4.

4.6 Fertility, pregnancy and lactation

This medicine can be administered during pregnancy and lactation if necessary.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The use of isotonic Sodium Chloride 0.9% solution for infusion can induce hypernatremia and hyperchloremia.
When infused through a peripheral vein over a long time thrombophlebitis can occur.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance. Website: www.hpra.ie.

4.9 Overdose

In the event of accidental over-infusion, general adverse effects of sodium excess in the body include nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivation and lacrimation, sweating, fever, tachycardia, hypertension, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma, and death.
Excessive administration of sodium chloride may cause hypernatremia and should be treated by an attending specialist physician.

Excess chloride in the body mass cause a loss of bicarbonate with an acidifying effect. When Sodium Chloride 0.9 %, solution for infusion, is used as a diluent for injectable preparations of other drugs, the signs and symptoms of over infusion will be related to the nature of the additives being used. In the event of accidental over infusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant and supportive measures should be provided as necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

PLASMA SUBSTITUTES AND SOLUTIONS FOR INFUSION/ELECTROLYTES SOLUTION/SODIUM CHLORIDE (ATC code :BO5XA03)

The pharmacodynamic properties of the solution are those of the sodium and chloride ions in maintaining the fluid and electrolyte balance. Ions, such as sodium, circulate through the cell membrane using various mechanisms of transport, among which is the sodium pump (Na-K-ATPase). Sodium plays an important role in neurotransmission and cardiac electrophysiology, and also in its renal metabolism.

5.2 Pharmacokinetic properties

Sodium is predominantly excreted by the kidney, but there is extensive renal reabsorption.
Small amounts of sodium are lost in the faeces and sweat.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection
Sodium hydroxide (for pH adjustment)
Hydrochloric acid, concentrated (for pH adjustment).

6.2 Incompatibilities

Check for any possible change in colour or formation of precipitate, insoluble complex or crystals.
Before adding any medicine, check that the pH range in which it is effective corresponds to that of 0.9 % sodium chloride solution (pH = 4.5 – 7.0).
Once a medicine is added to this solution, the mixture must be administered immediately.

6.3 Shelf life

Glass bottles:
Unopened: 5 years
Once opened: Use immediately.

Perfuflex bags:
Unopened 50 ml: 1 year

Unopened 100 ml: 18 months
Unopened 250 ml, 500 ml, 1000 ml: 2 years
Once opened: Use immediately.

Polypropylene/Styrene-Ethylene-Butadiene bags:
Unopened: 2 years.
Once opened: Use immediately.

Polyester-polyethylene copolymer-polypropylene/Styrene-Ethylene-Butadiene bags:
Unopened: 50 ml, 100 ml: 2 years.
Unopened: 250 ml, 500 ml, 1000 ml: 3 years.
Once opened: Use immediately.

Polypropylene/SIS-polypropylene/SEB bags:
Unopened: 50 ml, 100 ml, 250 ml, 500 ml, 1000 ml: 2 years.
Once opened: Use immediately.

Polyethylene bottles:
Unopened: 3 years.
Once opened: Use immediately.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

1 and 20 x 250 ml, 1 and 15 x 500 ml or 1 and 8 x 1000 ml in polypropylene/styrene, ethylene, butadiene bag with overwrap.
1 and 40 x 250 ml, 1 and 20 x 500 ml or 1 and 10 x 1000 ml in polypropylene/styrene, ethylene, butadiene bag without overwrap.

Polypropylene/SIS-polypropylene/SEB bags with overwrap: 50 ml, 100 ml, 250 ml, 500 ml, 1000 ml.

1 x 50ml, 40 x 50ml, 60 x 50ml, 65 x 50ml, 70 x 50ml.
1 x 100 ml, 40 x 100 ml, 50 x 100 ml, 55 x 100 ml, 60 x 100 ml.
1 x 250ml, 20 x 250 ml, 30 x 250 ml, 35 x 250 ml, 40 x 250 ml.
1 x 500 ml, 15 x 500 ml, 20 x 500 ml.
1 x 1000 ml, 8 x 1000 ml, 10 x 1000 ml.

Polypropylene/SIS-polypropylene/SEB bags with vial adapter port with overwrap : 50 ml, 100 ml, 250 ml, 500 ml, 1000 ml.
1 x 50 ml, 40 x 50 ml, 60 x 50 ml, 65 x 50 ml, 70 x 50 ml,
1 x 100 ml, 40 x 100 ml, 50 x 100 ml, 55 x 100 ml, 60 x 100 ml,
1 x 250 ml, 20 x 250 ml, 30 x 250 ml, 35 x 250 ml, 40 x 250 ml,
1 x 500 ml, 15 x 500 ml, 20 x 500 ml,
1 x 1000 ml, 8 x 1000 ml, 10 x 1000 ml

Not all pack sizes are marketed.

6.6 Special precautions for disposal and other handling

Do not use unless the solution is clear and free from particles and the container is undamaged.
Discard any damaged or partially used container.

Precautions when using bags:

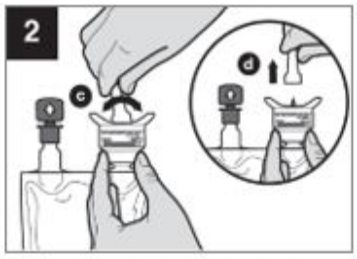
- do not use an air entry.
- flush the infusion system in order to avoid any passage of air.
- for single use only.
- do not reconnect partially used container.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

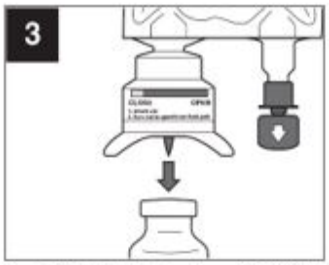
Preparation instructions prior to administration – bags with vial adapter:
Only for Single Dose Powdered or Liquid (up to 10 mL) Drug Vials with 20mm Closures
Use Aseptic Technique

Assembly

- **Remove the Vial Cover.**
  a. Remove the Vial Cover.
  b. Disinfect the stopper.



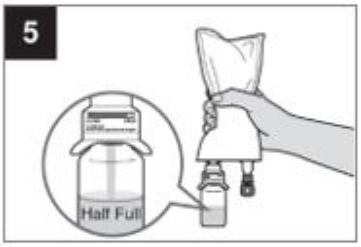
- **Tilt and pull the Vial Adapter Cap to remove.**
  c. Gently tilt the Adapter Cap back and forth to break the seals and dislodge it from place.
  d. Once dislodged, pull the Adapter Cap straight off.
  e. **Check the Vial Adapter for any moisture.** Discard if moisture is found.



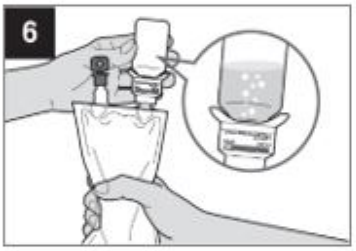
- **Push Vial Adapter down into the top of the Vial.**
  f. Hold the Vial upright firmly.
  g. Push the Adapter down into the Vial until it snaps in place.
  DO NOT TWIST.
  h. Lightly pull the Vial to ensure it is completely secure.
  i. Squeeze the Bag and check that the Vial is still dry.
  j. Use only if Vial is fully secure and dry.

Reconstitution

- **Turn the Vial to the right to open.**
  k. Turn the Vial to the right until the Yellow Indicator is in the OPEN position.



- **For a powdered Drug Vial, squeeze the Bag until the Vial is half full of solution.**
  Note: For liquid Drug Vials, skip Step 5 and proceed directly to Step 6.
  l. Hold the Bag, keeping the Vial upright.
  m. Squeeze the Bag until Vial is **half full** of solution.
  n. Shake the Vial to suspend the drug in solution.



- **With the Vial upside down, squeeze and release the Bag to drain the solution from the Vial.**
  o. Turn the bag so the Vial is upside down.
  p. Squeeze the Bag to force air into the Vial.
  q. Release the Bag to drain the suspended drug from the Vial into the Bag.
  r. Repeat steps 5 and 6 until the Vial is **empty** of drug and solution is thoroughly mixed. **Ensure drug is completely dissolved.**

Do not remove the Drug Vial.

- **Turn the Vial to the left to close.**
  s. Turn the Vial to the left until the Yellow Indicator is in the CLOSE position to prevent backflow.

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7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1
Bad Homburg v.d.H 61352
Germany

8 MARKETING AUTHORISATION NUMBER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd August 2003
Date of last renewal: 28th August 2007

10 DATE OF REVISION OF THE TEXT

June 2023