PACKAGE LEAFLET: INFORMATION FOR THE USER

Sodium Chloride 0.9 % w/v Solution for Infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Sodium Chloride 0.9%Solution for Infusion is and what it is used for

Sodium Chloride 0.9% is a sterile, colourless solution for infusion.
It is used for the treatment of sodium depletion (deficiency), dehydration (water loss), hypovolaemia (sudden drop in volume of circulating blood) and as a solvent and carrier for other compatible drugs for parenteral administration of medicines.

2. What you need to know before you use Sodium Chloride 0.9 % Solution for Infusion

Do not use Sodium Chloride 0.9 % Solution for Infusion:
- if you have water/sodium retention situations, and in particular :
    - decompensated heart failure (heart can't pump enough blood throughout the body)
    - kidney failure with oliguria or anuria (decreased or absent production of urine).

Furthermore, when Sodium Chloride 0.9 % Solution for Infusion is used as a carrier for other medicines, your doctor will consider contraindications related to the added medicinal product(s) before administering this medicine to you. Your doctor will explain this to you.

Warnings and precautions

Sodium Chloride 0.9 % Solution for Infusion, will be used with caution if you suffer from:
- high blood pressure,
- heart failure
- severe liver function (with swelling and excess liquid)
- fluid in the lungs (pulmonary oedema)
- abnormal build-up of fluid in the ankles, feet, and legs (peripheral oedema)
- impaired kidney function
- are pregnant and have been told you suffer from pre-eclampsia

- suffer from aldosteronism (overproduction of the hormone aldosterone from the cortex [the outer layer] of the adrenal gland)

Your doctor will check these before you are given infusion with Sodium Chloride 0.9 % Solution for Infusion.
The doctor or nurse will ensure that the infusion is given to you properly.

Other medicines and Sodium Chloride 0.9 % Solution for Infusion:
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding
Sodium Chloride 0.9 % Solution for Infusion, can be used during pregnancy or breast-feeding.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine, especially if you suffer from pre-eclampsia.

Driving and using machines
Not relevant.

3. How to use Sodium Chloride 0.9 % Solution for Infusion

You will receive your medicine by slow intravenous infusion ('IV drip').
The rate at which the infusion is given and the volume infused will depend on your own specific requirements. Your doctor will decide on the correct dose for you to receive.

If you use more Sodium Chloride 0.9 % Solution for Infusion than you should

In the event of accidental over-infusion, general adverse effects of sodium excess in the body include nausea, vomiting, diarrhoea, abdominal cramp, thirst, reduced salivation and tear production, sweating, fever, tachycardia, hypertension, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscle twitcing and rigidity, convulsions, coma and death.

Excessive administration of sodium chloride may cause hypernatraemia and should be treated by an attending specialist physician.

Excessive chlorides 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, your treatment will be discontinued and you will be observed for the appropriate signs and symptoms related to the drug administered. You should be provided the relevant and supportive measures as necessary.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been observed:

- hypernatremia (too much sodium in the blood) and hyperchloremia (too much chloride in the blood)
- swelling of a vein caused by a blood clot may occur where the infusion is given.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sodium Chloride 0.9 % Solution for Infusion

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
[For glass Bottles and polyethylene bottles] : no special storage conditions.
[For flexible Bags] : do not store above 25°C.
Your doctor or nurse will ensure the solution is clear and free from particles before use.
Any solution remaining after treatment should be discarded.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6. Contents of the pack and other information

What Sodium Chloride 0.9 % Solution for Infusion contains
- The active substance is :
Sodium chloride: .....9 g/l

Sodium: .....154 mmol/l
Chloride:.....154 mmol/l
Osmolality:.....290 mosmol/kg
Osmolarity:.....308 mosmol/l

pH between 4.5 and 7.0.

- The other ingredients are : hydrochloric acid, concentrated, sodium hydroxide, water for injections.

What Sodium Chloride 0.9 % Solution for Infusion looks like and contents of the pack

Sodium Chloride 0.9% w/v solution for infusion is a clear and colourless solution for infusion.

1, 30 × 125 ml filled at 50 ml; 1, 10, 30 × 125 ml filled at 100 ml; 1, 12 × 250 ml filled at 125 ml ; 1, 10, 30 × 125 ml ; 1, 10, 12 × 250 ml ; 1, 10, 12× 500 ml ; 1, 6 × 1000 ml glass bottle

1, 10, 40 x 100 ml; 1, 10, 20, 30 x 250 ml; 1, 10, 20 x 500 ml; 1, 10 x 1000 ml polyethylene bottles

1, 40, 60, 65, 70 × 50 ml ; 1, 40, 50, 55, 60 × 100 ml ; 1, 20, 25, 30, 35, 40 × 250 ml ; 1, 15, 20 × 500 ml ; 1, 8, 10 × 1000 ml bags.

Not all pack sizes may be marketed.

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

Manufacturer :
FRESENIUS KABI FRANCE
6, rue du rempart
F - 27400 Louviers

FRESENIUS KABI DEUTSCHLAND
Freseniusstraße 1
D - 61169 Friedberg

FRESENIUS KABI NORGE AS
Svinesundsveien 80
1788 Halden
Norway

This leaflet was last approved in 01/2024.

The following information is intended for medical or healthcare professionals only:

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 or 17.1 mmol of 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.

Contraindications

This medicine should not be administrated case of in 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.

Special warnings and precautions for use

Special warnings:

Sodium chloride 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 0.9% sodium chloride solution 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 0.9% sodium chloride solution, the mixture must be administered immediately.

Instructions for use and 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.
Use in aseptic conditions.

Precautions when using bags:

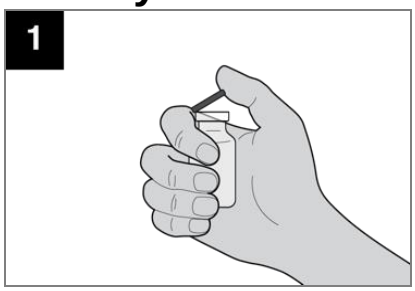
- do not use an air entry.
- flush the infusion system in order to avoid any passage of air.
- do not connect in series since the residual of the first container might be carried on by the solution coming form the second container, with the risk of air embolism.
- for single use only; do not reconnect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

Preparation instructions prior to administration – bags with vial adapter:

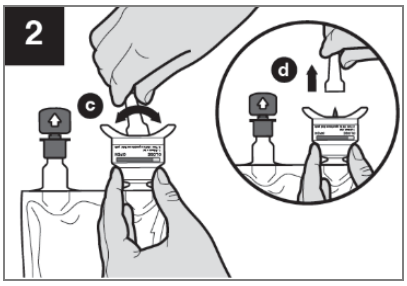
Only for Single Dose Powdered or Liquid (up to 10 mL) Drug Vials with 20mm Closures

Use Aseptic Technique

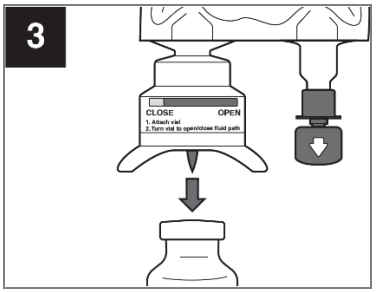
Assembly



- **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.

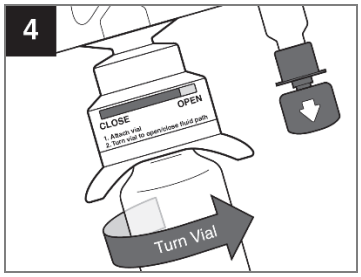


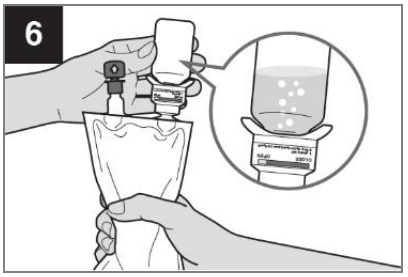
- **Push Vial Adapter down into the top of the Vial.**
  f. Hold the Vial upright firmly.
  g. Push the Adapter down into the Vial until it snaps in place.

DO NOT TWIST.

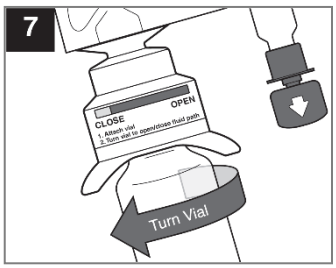
  h. Lightly pull the Vial to ensure it is completely secure.
  i. Squeeze the Bag and check that the Vial is still dry.
  j. Use only if Vial is fully secure and dry.

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.



- **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.

- **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.