Package leaflet: Information for the user

Sodium Chloride 0.9% w/v solvent for parenteral use

Sodium chloride

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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Sodium Chloride is and what it is used for

Sodium Chloride is indicated as a solvent of medicines that should be administered intravenously, intramuscularly or subcutaneously as a support of the addition of medicines.

2. What you need to know before you use Sodium Chloride

Do not use Sodium Chloride
- If you have had some allergic or unusual reaction to sodium chloride.
- If you have a high concentration of sodium in your blood (hypernatremia)
- 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

Talk to your doctor or nurse before using Sodium Chloride.
- Once opened the solutions should be used immediately.
- In case of subcutaneous administration do not add any supplement, since isotonia would change.
- Do not use the solution if it is not transparent and without precipitates.
- Make sure about the physic-chemic compatibility when adding any medicine to the ampoule.
- Addition of alcohol to sodium chloride solutions should be avoided.

Children

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.

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, hypoproteinemia and other sicknesses and treatments (eg. corticosteroids) associated to sodium retention.

Other medicines and Sodium Chloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Interactions with other medicines depend on the medicine to be added.

Sodium chloride 0.9% w/v solution presents incompatibilities with hydrocortisone, amphotericin B, tetracyclines, cephalotin, erythromycin, lactobionate and lithium salts.

It is incompatible with active ingredients not soluble in sodium chloride solution, because an eventual precipitation of the active ingredient, as well as with medicines which stability or solubility demands a very acid or very alkaline pH.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

Due to the characteristics of the preparations, no effect on pregnant women or in lactation period should be expected, as long as the administration is correct and controlled.

Driving and using machines

There is no evidence that this product could affect the ability to drive or use machines.

3. How to use Sodium Chloride

Follow these instructions unless your doctor has given you different ones.

Sodium Chloride is to be administered intravenously, intramuscularly or subcutaneously.

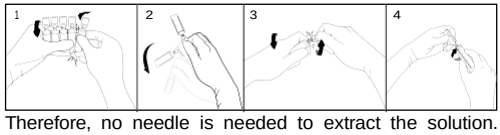
It is not necessary to aseptisize the bottle before its opening.

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 conservator or bactericide, so open and unused ampoules should be discarded immediately.

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

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Your doctor will tell you the duration of your treatment with these medicines.

If you think that the action of Sodium Chloride is too strong or weak tell your doctor.

If you use more Sodium Chloride than you should
If you have received more Sodium Chloride than you should tell your doctor immediately.

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

Nevertheless, 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.

In case you have some symptom of intoxication, the administration will be discontinued and a symptomatic treatment will be established.

In children, coma and convulsions can persist until vascular lesions are produced. Respiratory distress with tachypnea and red nose can also appear.

In case of overdose or accidental ingestion, go immediately to a medical centre or call to Toxicological Information Service.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.
If the product is administered correctly no effect should be expected.

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

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

Side effects can also be related to the added medicine.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail:medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sodium Chloride
Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the container after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening: immediate use.

6. Contents of the pack and other information
What Sodium Chloride contains
- The active ingredient is Sodium chloride. Each 100 ml contain 0.9 g of sodium chloride.
- The excipients are water for injections, hydrochloric acid and sodium hydroxide.

Centesimal composition:

		Electrolytes	mmol/l	mEq/l
Sodium chloride	0.9 g	Na^+	154	154
Water for injections q.s.p.	100 ml	Cl^-	154	154

Osmolarity: 308 mOsmol/l.

What Sodium Chloride looks like and contents of the pack
Sodium Chloride 0.9% w/v solvent for parenteral use is a clear and colourless solution, free or practically free from particles.

Sodium chloride is a solvent for parenteral use presented in the following formats:

Package with 20 ampoules containing 5 ml
Package with 50 ampoules containing 5 ml
Package with 20 ampoules containing 10 ml
Package with 50 ampoules containing 10 ml
Package with 20 ampoules containing 20 ml

Not all pack-sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Marketing Authorisation Holder
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1,
61352 Bad Homburg v.d.Höhe
Germany

Manufacturer
FRESENIUS KABI ESPAÑA, S.A.
C/ Marina 16 – 18, planta 17
08005 Barcelona, Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	Name of the medicinal product
Belgium	Natriumchloride 0,9% Fresenius Kabi oplosmiddel voor parenteraal gebruik
Czech Republic	0,9% Sodium Chloride Kabi
Estonia	Sodium chloride Kabi 0,9%, süsteravimi lahusti
Greece	Sodium Chloride 0.9%/Fresenius
Hungary	Nátrium-klorid Kabi 0,9% oldószer parenterális készítményekhez
Ireland	Sodium Chloride 0.9% w/v Solvent for Parenteral Use
Lithuania	Sodium Chloride Kabi 0,9 % tirpiklis parenteriniam vartojimui
Latvia	Sodium chloride Kabi 0,9% šķīdinātājs parenterālai lietošanai
Poland	Natrium chloratum 0,9% Kabi, 9 mg/ml, rozpuszczalnik do sporządzania leków parenteralnych
Romania	Ser fiziologic 9 mg/ml Kabi solvent pentru uz parenteral
Slovak Republic	0,9 % Sodium Chloride Kabi
Slovenia	Natrijev klorid Fresenius Kabi 9 mg/ml
Spain	Cloruro de sodio Meinsol 9 mg/ml disolvente para uso parenteral

This leaflet was last revised in **February 2019**

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