SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.9% - Fresenius

Solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Sodium chloride 9 mg
Water for injection to 1 ml

Osmolarity 308 mOsmol/L.

3. PHARMACEUTICAL FORM

Solution for injection
Clear and colourless solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Vehicle or diluent for parenteral administration of medicines for intravenous route.

4.2 Posology and method of administration

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

4.3 Contraindications

Due to the indications of the product, contraindications depend on the medicine to be dissolved.
In general, the administration of this product is contra-indicated in the following situations:

- Hypernatremia
- Hypercholeremia
- 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

Once the container is opened the solution should be used immediately.
Do not use the solution if it is not clear and without precipitates.
Before adding the medicine to the ampoule compatibility between the substance to be administered and sodium chloride should be checked.
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 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.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions depend on the medicine to be dissolved.
Sodium chloride has incompatibility with lithium carbonate, whose renal excretion is directly proportional to sodium levels in the body.

Administration of sodium chloride accelerates renal excretion of lithium, leading to a decrease of Lithium therapeutical action.

The addition of alcohol to sodium chloride solutions should be avoided. Corticoserotids are associated with the retentions of sodium and water, with edema and hypertension. Disturbances of electrolyte balance are common with naturally occurring corticosteroids such as cortisone and hydrocortisone, but are less frequent with many synthetic glucocorticoids, which have little or no mineralocorticoid activity.

4.6 Pregnancy and lactation

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.

Data of several exposed pregnancies that appear in scientific literature indicate that maternal infusion of sodium chloride solutions during pregnancy do not provoke adverse reactions for foetus or newborn health. Likewise there is no evidence that maternal administration of saline physiologic administration during lactation period is harmful for newborn. Up to now, there are no other relevant epidemiological data available, neither related with pregnancy nor with lactation; therefore it is recommended to be used with precaution if it is administered during those periods.

4.7 Effects on ability to drive and use machines

There is no evidence that sodium chloride 9 mg/ml solution can affect the ability to drive or use machines.

4.8 Undesirable effects

General disorders and administration site conditions can be provoked. 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.
When Sodium chloride 9 mg/ml, 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 adverse reactions due to the associated medicine are shown, 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 in case it was necessary.
Adverse reactions may be associated to the technique of administration including febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.
Rare case of central pontine myelinolysis (a potentially severe of lethal demyelinating disorder to the central nervous system) have been reported.

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.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il/
and emailed to the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com

4.9 Overdose

When Sodium Chloride 0.9% is used as a diluent for injectable preparations of other drugs, the signs and symptoms of over dose will be related to the nature of the additives being used.
In the event of overdose, 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
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 intern organs, nausea, vomiting, diarrhea, abdominal cramps, thirst, decrease of salivation and lacrimation, sweating, fever, hypotension or hypertension, tachycardia, renal failure, peripheral and pulmonary oedema, acidosis, respiratory insufficiency, respiratory arrest, headache, vertigo, restlessness, irritability, weakness, muscle spasms, rigidity, convulsions, coma and death.
In children, coma and convulsions can persist until vascular lesions are produced, respiratory distress with tachypnea and red nose can also appear.
In case the excess of ingestion of sodium chloride is recent, emesis

should be induces or a gastric wash should be performed. Convulsions will be treated with intravenous diazepam.
Normal serum levels should be restored administering 10 - 15 mmol daily of an intravenous hypotonic saline solution.
In case of an important renal damage, if the patient is dying or if serum sodium concentration is higher than 200 mmol/L, a treatment with dialysis should be performed.
Excessive administration of sodium chloride may cause hypernatremia and should be treated by an attending specialised physician Excess chloride in the body may cause a loss of bicarbonate with an acidifying effect.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: B05XA03. Electrolyte solutions

Sodium Chloride 0.9% intravenous injection is an isotonic solution, with an approximate osmolarity of 308m0sm/l.

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 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 feces and sweat.

5.3 Preclinical safety data

Safety of isotonic sodium chloride solutions is sufficiently recognized in fluidotherapy field in the entire world, thank to the existing experience related to the use of this solution as restorer of hydroelectrolytic balance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections.

6.2 Incompatibilities

As with all parenteral solutions compatibility of the additives with the solution must be assessed before addition. Additives known to be incompatible should not be used.
It is incompatible with hydrocortisone, amfotericine B, tetracyclines, cefalotine, erythromycin, lactobionate and lithium salts.
It is 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 the product: 36 months
Shelf life after first opening: immediate use

6.4 Special precautions for storage

Store below 25ºc

6.5 Nature and contents of container

Low density polyethylene (LDPE) ampoules: 5 ml, 10ml, 20ml ampoules.

7. Manufacturer

LABESFAL - Laboratories Almiro S.A.
Fresenius Kabi Group.
Lagedo, Santiago de Besteiros, 3465 -157, Portugal

8. MARKETING AUTHORISATION HOLDER

Neopharm (Israel) 1996 Ltd
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9. MARKETING AUTHORISATION NUMBER(S)

155.78.34366.00

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