Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sodium chloride 0.9% w/v solvent for parenteral use

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per 100 ml:

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

Each ml of solution contains 9 mg of sodium chloride

Osmolarity: 308 mOsmol/L.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solvent for parenteral use.
Clear and colourless solution, free or practically free from particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Vehicle or diluent for parenteral administration of medicines for intravenous, intramuscular or subcutaneous route.

4.2 Posology and method of administration

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

Method of administration
Intravenous, intramuscular or subcutaneous use.

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 contraindicated in the following situations:

§ Hypernatremia
§ 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.

In case of subcutaneous administration no supplement should be added, since isotonia would change.

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 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 (e.g. corticosteroids) associated to sodium retention.

4.5 Interaction with other medicinal products and other forms of interactions

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, giving a decrease of therapeutical action of this.

The addition of alcohol to sodium chloride solutions should be avoided.

4.6 Fertility, 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 sodium chloride 9 mg/ml solution 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

Not relevant.

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 0.9% w/v 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.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: http://www.hpra.ie/; E-mail:medsafety@hpra.ie.

4.9 Overdose

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.

Paediatric population
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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solvent and diluent agents including solutions for irrigation, ATC code: V07AB

Sodium chloride, main salt involved in extracellular fluid tonicity, is used for the treatment of extracellular volume reduction, in case of dehydration and when a sodium lack is produced, as it happens in cases of excessive diuresis, gastroenteritis or for a reduction in the consumption of salt.

Sodium, essential and irreplaceable, is the main cation in extracellular fluid and the most important osmotic component in the control of volemia. Chloride ion, can be substituted for bicarbonate, always available as carbonate dioxide for cellular metabolism.

Sodium chloride 0.9% w/v solvent for parenteral use presents the same osmotic pressure as body fluids.

In case of mild alkalosis the administration of physiologic saline solution will allow the restoration of chloride ion lost, whist bicarbonate excess will excreted in urine, with the consequent decrease and normalization of alkaline reserve

Likewise, isotonic sodium chloride solution is a suitable vehicle for the administration of several medicines and electrolytes.

5.2 Pharmacokinetic properties

Absorption
Due to the intravenous administration of the product there will not be any absorption.

Distribution
Electrolytes sodium and chloride are distributed, mainly in extracellular fluid. As physiologic saline solution is isotonic the administration of this solution will not provoke any change in osmotic pressure of extracellular fluid, so there will not be any circulation of water to intracellular compartment and both ions will not practically penetrate in the cell.

Nevertheless, a decrease (for dilution) on oncotic pressure of plasmatic proteins will be produced, and this will provoke the circulation of water to interstitial compartment through capillary walls, and normality could be reached.

It should be taken into account that the richest tissue in water is muscles, whilst sodium is mainly found in bounds, constituting one of the main reserves of bones.

Elimination

Sodium ion is mainly eliminated through kidney (95%) and the rest through the skin (sweat) and digestive system.

Water is eliminated through kidney, skin, lungs and digestive system.

Therefore kidney is the most important organ in the maintenance of concentration of extracellular sodium. The amount being excreted of this cation will depend on the needs of the body.
Urine with concentrations lower that 1 mEq sodium/L could even be produced.

5.3 Preclinical safety data

Safety of isotonic sodium chloride solutions is sufficiently recognized in the fluid therapy field in the entire world, thanks to the existing experience related to the use of this solution as a restorer of hydroelectrolytic balance

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Water for injections.

6.2 Incompatibilities

Before the content of the ampoule is added to the medicine the compatibility between the added products should be checked.

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 incompatiblewith medicines for which a very acid or very alkaline pH is necessary for their stability or solubility.

6.3 Shelf life

Shelf life of the product: 2 years
Shelf life after first opening: immediate use

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Low density polyethylene (LDPE) ampoules.

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

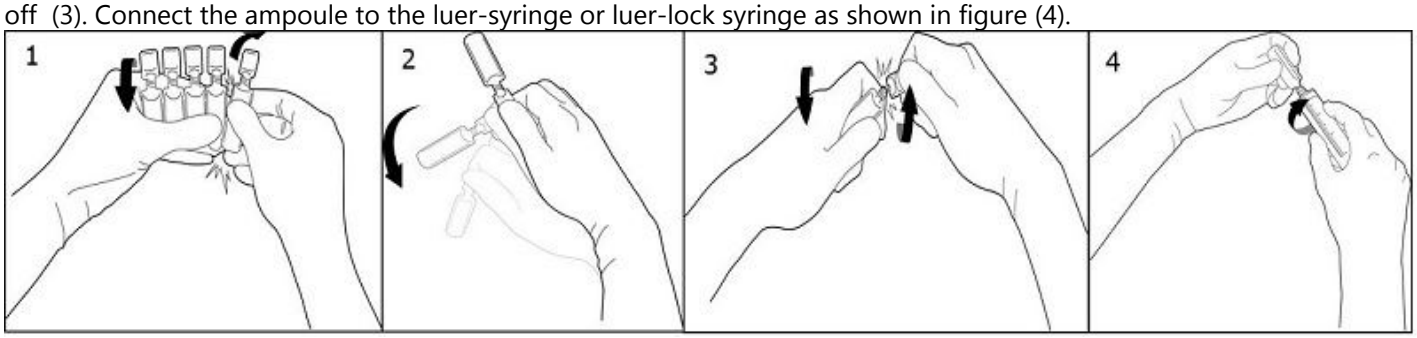
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

It is not necessary to sterilise 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 preservative or bactericide, so open and unused ampoules should be discarded immediately.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA2059/063/006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th August 2009
Date of last renewal: 21st June 2012

10 DATE OF REVISION OF THE TEXT

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