Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.9% w/v Solution for Infusion, polyethylene bottle

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 interactions

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

No particular data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection
Sodium hydroxide
Hydrochloric acid

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

2 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Polyethylene bottle:
100ml, 250 ml, 500 ml, 1000 ml, 1000 ml.

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

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA2059/063/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th August 2009
Date of renewal: 25th October 2013

10 DATE OF REVISION OF THE TEXT

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