SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.9% solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium chloride	0.9%w/v

Electrolytes:

Na^+	154 mmol/l
Cl^-	154 mmol/l

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection

A clear colourless solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium Chloride 0.9% solution for injection is used as a solvent and carrier solution for injectable drugs.

4.2 Posology and method of administration

Posology

As required

Method of administration

Intravenous, intramuscular or subcutaneous use

4.3 Contraindications

None stated.

4.4 Special warnings and precautions for use

If Sodium Chloride 0.9% solution for injection is to be administered subcutaneously be aware that any additions to the isotonic normal saline solution could render it hypertonic and thus cause pain at the injection site.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

None stated

4.7 Effects on ability to drive and use machines

No studies on the ability to drive and use machines have been performed.

4.8 Undesirable effects

None stated.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

No particulars stated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: B05XA03

Sodium chloride 0.9% solution shows the same osmotic pressure as body fluids.

The isotonic solution of sodium chloride is a suitable vehicle for administration of a large number of drugs and electrolytes.

5.2 Pharmacokinetic properties

Sodium and chloride electrolytes distribute, primarily, in the extracellular fluid. Because the physiological saline solution is isotonic, its administration will not produce a change in the osmotic pressure of the extracellular fluid, whereby water will not pass into the intracellular compartment and both ions will practically enter the cell.

5.3 Preclinical safety data

Safety of sodium chloride isotonic solutions is adequately recognized in the fluid therapy field worldwide, thanks to a wide experience available in the use of this solution as a restorer of the hydro-electrolytic balance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections
Sodium hydroxide for pH adjustment.
Hydrochloric acid for pH adjustment.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

a) Shelf life of the product as packaged for sale:

Shelf life of the pharmaceutical product: 2 years

b) Shelf life after first opening of the container :

The product should be used immediately after opening.

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 ampoules (LDPE).

- Carton with 20 ampoules of 5 ml
- Carton with 20 ampoules of 10 ml
- Carton with 20 ampoules of 20 ml
- Carton with 50 ampoules of 10ml

- Carton with 100 ampoules of 10ml

6.6 Special precautions for disposal and other handling

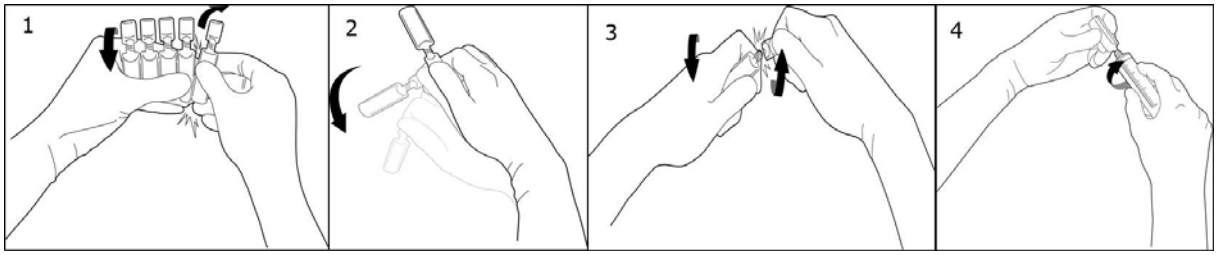
It is not necessary to sterilise the bottle before its opening.

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 Limited
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8. MARKETING AUTHORISATION NUMBER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/08/2007

10 DATE OF REVISION OF THE TEXT

10/12/2018