SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 1.8% Intravenous Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride 1.8% Intravenous Infusion has the following composition:

Name	Specification Reference	%w/v
Sodium Chloride	EP	1.8

3 PHARMACEUTICAL FORM

Intravenous fluid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium Chloride 1.8% Intravenous Infusion is used in the treatment of acute sodium deficiency and water intoxication.

4.2. Posology and Method of Administration

Adults and Children
The rate of administration and volume infused will depend upon the requirements of the individual patient and the judgement of the physician

Elderly
Care should be taken to avoid circulatory overload, particularly in patients with cardiac and renal insufficiency.

For intravenous infusion.

4.3. Contra-indications

Patients with sodium overload. This may occur with myocardial and renal damage, but it should also be appreciated that in the first five or six days after surgery or severe trauma there may be an inability to excrete unwanted sodium.

4.4. Special Warnings and Precautions for Use

Caution is necessary when considering the use of this solution in patients with cardiac failure, hypertension, impaired renal function and peripheral or pulmonary oedema and toxaemia of pregnancy

The label states: Do not use unless the solution is clear and free from particles.

4.5. Interactions with other Medicaments and other forms of Interaction

No clinically significant interactions known.

4.6. Pregnancy and Lactation

The safety of Sodium Chloride 1.8% Intravenous Infusion during pregnancy and lactation has not been assessed, but its use during these periods is not considered to constitute a hazard.

4.7. Effects on Ability to Drive and Use Machines

Not applicable.

4.8. Undesirable Effects

Thrombosis of the chosen vein is always a possibility with intravenous infusion. If infusion is protracted then another vein should be selected after 12 - 24 hours.

4.9. Overdose

Overdosage may lead to fluid overload, electrolyte imbalance, in particular hypematraemia.

Treatment should consist of discontinuing the infusion and, if necessary administering a diuretic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium chloride provides a source of sodium and chloride ions to maintain the osmotic tension of the extracellular fluid and tissues.

5.2. Pharmacokinetic Properties

No data available.

5.3. Preclinical Safety Data

N/A

Pharmaceutical Particulars

6.1. List of Excipients

Name	Specification Reference	%w/v
Water for Injections in bulk	EP	TO 100
Hydrochloric Acid	EP	QS
Sodium Hydroxide	BP	QS

6.2. Incompatibilities

Incompatible with amiodarone, amphotericin B, amsacrine and sodium nitroprusside.

6.3. Shelf Life

36 months.

6.4. Special Precautions for Storage

Store at 2° to 25°C

6.5. Nature and Contents of Container

Sealed semi-rigid, cylindrical neutral polythene container with a 'Twist-off' seal at one end and a ring tab at the opposite end.

The container is overwrapped in polyethylene.

6.6. Instruction for Use/Handling

Do not dilute before use.
Use standard sterile peritoneal dialysis equipment.

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Limited
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8. Marketing Authorization Number

PL 08828/0053

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 25th April 1989
Date of Renewal of Authorisation: 16th November 1994

10 DATE OF REVISION OF THE TEXT

22/02/2010