SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.45% Intravenous Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride 0.45% Intravenous Infusion has the following composition:

Name	Specification Reference	%w/v
Sodium Chloride	EP	0.45

3 PHARMACEUTICAL FORM

Intravenous fluid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium Chloride 0.45% Intravenous Infusion is used in the treatment of dehydration associated with hyperosmolarity (Hypernatraemia)

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.

The effect of saline therapy on dehydration can often be assessed from relief of symptoms, observation of blood pressure and measurement of the volume and concentration of urine output.

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

For intravenous infusion.

4.3. Contra-indications

Intravenous saline solutions may be contra-indicated in patients with impaired renal or cardiac function.

4.4. Special Warnings and Precautions for Use

Saline solutions should not be administered rapidly or for prolonged periods particularly in infants and the elderly. In potassium deficient patients administration of saline will increase potassium loss, so that if it is given, potassium supplements should also be given. The solution is hypotonic.

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

4.5. Interactions with other Medicaments and other forms of Interaction

No clinically significant reactions.

4.6. Pregnancy and Lactation

The safety of the solution 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 and electrolyte imbalance. 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

Not applicable

5.3. Preclinical Safety Data

None

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections in bulk
Hydrochloric Acid
Sodium Hydroxide

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.

Pack size: 500ml

6.6. Instruction for Use/Handling

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

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Limited
Cestrian Court
Eastgate Way
Manor Park
Runcorn
Cheshire
WA7 1NT

8 MARKETING AUTHORISATION NUMBER(S)

PL 08828/0018

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 20th April 1989
Date of Renewal of Authorisation: November 1999

10 DATE OF REVISION OF THE TEXT

22/02/2010