SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 5% Intravenous Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride 5% Intravenous Infusion has the following composition:

Name	%w/v
Sodium Chloride	5.0

3 PHARMACEUTICAL FORM

Intravenous fluid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium Chloride 5% 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 Contraindications

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

Sodium Chloride 5% Intravenous Infusion is not suitable for protracted use unless there is heavy continued loss of electrolytes; even then it should be used with care.

Saline solutions should not be administered rapidly or for prolonged periods particularly in infants and the elderly.

A too rapid injection of hypertonic saline may cause sudden cardiac arrest or circulatory overloading.

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 hypertonic.

Restrict intake in impaired renal function, cardiac failure, hypertension, peripheral and pulmonary oedema, toxaemia of pregnancy. This guidance is particularly relevant for isotonic and hypertonic forms.

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

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions.

4.6 Fertility, 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, 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

Not applicable.

5.3 Preclinical safety data

None stated.

6 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

500 ml polyethylene container - 36 months

500 ml polyolefin bag – 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

Or

A flexible 500 ml polyolefine bag sealed in a polyolefine overwrap.

6.6 Special precautions for disposal

Polyfusor:

Do not dilute before use.

Use standard sterile peritoneal dialysis equipment.

free*flex*

Opening the overwrap

Locate the corner tabs at the end of the bag. Grip the two tabs and pull the two halves of the overwrap apart, releasing the bag onto a clean surface.

Setting up the solution

Position the roller clamp of the giving set to just below the drip chamber and close.

Hold the base of the giving set port firmly and grip the wings of the twist off tab. Twist to remove the protective cover.

Still holding the base of the giving –set port push the set spike, fully into the port to ensure a leak proof connection.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

PL 08828/0051

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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