# 1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.9% Intravenous Infusion

# 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The product has the following composition:

| Name | Specification Reference | %w/v |
|---|---|---|
| Sodium Chloride | EP | 0.9 |

# 3 PHARMACEUTICAL FORM

A clear, colourless liquid, practically free from particles.

# 4 CLINICAL PARTICULARS

## 4.1 Therapeutic indications

Sodium Chloride 0.9% Intravenous Infusion is used in the treatment of dehydration to correct water and electrolyte depletion.

For intravenous infusion.

## 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

## 4.3. Contra-indications

Patients with sodium overload. It is well known that 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 0.9% 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. In potassium deficient patients administration of normal saline will increase potassium loss, so that if it is given, potassium supplements should also be given.

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

Do not use unless solution is clear and free from particles.
Keep medicines out of the reach of children.

## 4.5. Interactions with other Medicaments and other forms of Interaction

No clinically significant drug interactions known.

## 4.6. Pregnancy and Lactation

The safety of Sodium Chloride 0.9% Intravenous Infusion during pregnancy and lactation has not been assessed, but its use during these periods is not considered 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. In particular hypernatraemia. Treatment should consist of discontinuing the infusion and if necessary administering a diuretic.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Sodium chloride provides essential 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

## 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

Incompatibilities with Amiodrone, Amphoteriocin B, Amascrine and Sodium Nitroprusside.

## 6.3 Shelf life

Semi-rigid, cylindrical neutral polythene container: 60 Months

Polyethylene bottle with cap and administration/addition points: 36 months

Polypropylene bottle with cap with an administration point and an addition point: 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 (500ml and 1000ml) with a 'Twist-off' seal at one end and a ring tab at the opposite end.

Or

Polyethylene bottle with cap (50, 100, 250, 500 and 1000ml) with an administration point and an addition point (KabiPac).

Or

Polypropylene bottle with cap (100, 250, 500 and 1000ml) with an administration point and an addition point (KabiClear).

## 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 08828/0034

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1/08/1989 / 17/09/2001

## 10 DATE OF REVISION OF THE TEXT

16/08/2017