SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride Infusion BP 0.9%, as Steriflex No. 1 or **free***flex*

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Steriflex No. 1 has the following composition:
Sodium Chloride for Injections 0.9% w/v

3 PHARMACEUTICAL FORM

Intravenous infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Steriflex No 1 is used in the treatment of dehydration to correct water and electrolyte depletion.

The smaller volume containers may be used as a diluent and delivery system when administering compatible additives so as to avoid the risk of any over dilution of the additive drug.

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.

Intravenous infusion.

The smaller volume containers may be used as a diluent and delivery system when administering compatible drug additives so as to avoid the risk of any over dilution of the additive drug.

4.3 Contraindications

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 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

This product is not suitable for protracted use unless there is heavy continued loss of electrolyte, 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 physician should also be alerted to the possibility of adverse reactions to drug additives diluted and administered in this container. Prescribing information for drug additives to be administered in this manner should be consulted.

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 this 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.

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.
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

Pharmacotherapeutic group: Plasma substitutes and solutions for infusion/electrolytes solution/sodium chloride
ATC code: BO5XA03

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

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Incompatible with Amiodarone, Amphotericin B, Amsacrine and sodium nitroprusside.

Because of the nature of the plastic material of the Steriflex bag (PVC) this solution should not be used as a vehicle for the administration of drugs which may be sorbed on to the bag to varying and significant degrees.

6.3 Shelf life

50, 100, 150 & 250ml PVC Bags - 18 months.
330, 500 & 1000ml PVC Bags – 24 months.
50, 100 & 150ml Polyolefin Bags – 24 months
250, 330, 500 & 1000ml Polyolefin bags – 36 months

6.4 Special precautions for storage

Store between 2 and 25°C

6.5 Nature and contents of container

The container is 50, 100, 150, 250, 330, 500 or 1000ml flexible bag made of medical grade PVC.

a) A hermetically sealed polythene bag.
b) A rectangular pouch consisting of polyamide/polythene composite
c) Polyamide/Polyethylene-Propylene composite laminate welded to polypropylene ethylene propylene composite, plugged with a polycarbonate plug with either a bromobutyl (West 4481/45) or gum (West 7006/45) stopper.

Or

A flexible 50, 100, 150, 250, 330, 500 or 1000ml polyolefine bag sealed in a polyolefine overwrap.

Not all pack sizes may be marketed

6.6 Special precautions for disposal

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 of 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. Prime the set in accordance with the manufacturer's instructions.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

PL 08828/0084

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 July 1989
Date of latest renewal: 03 February 1999

10 DATE OF REVISION OF THE TEXT

June 2021