1. NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.2% Sodium Chloride 0.9% IV Infusion BP, as Sterifiex No. 28 and free*flex*.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Steriflex No. 18 has the following composition:

Name	Specification Reference	%w/v
Potassium Chloride	EP	0.2
Sodium Chloride for Injections	EP	0.9

3. PHARMACEUTICAL FORM

Intravenous Infusion.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Potassium replacement therapy

4.2. Posology and Method of Administration

The volume and rate of infusion will depend upon the requirements of the individual patient and the judgement of the physician.

Adults

The rate of infusion should not exceed 10-20 mmol of potassium per hour. The total daily dosage of potassium should not exceed 200 mmol of potassium.

Children

Correspondingly reduced volumes and rates of infusion may be required.

Elderly
A reduced volume and rate of infusion may be necessary to avoid circulatory overload, particularly in patients with cardiac or real insufficiency.

For intravenous infusion.

4.3. Contra-Indications

Addison's disease, adrenal insufficiency, acute or chronic renal disease, oliguria, anuria and patients with hyperkalaemia. The intravenous infusion of glucose solutions may also be hazardous in patients with impaired hepatic function.

4.4. Special Warnings and Special Precautions for Use

Intravenous infusion must be carried out slowly. Caution should be used with administration to patients receiving digitalistherapy, patients with renal or adrenal insufficiency, cardiac disease acute dehydration or heat cramp, those recieving potassium sparing diurectics and patients with sickle cell haemoglobinopathy.

Caution should be exercised in the volume and rate of infusion since fluid overload and hyperkalaemia may comprise cardiac function. Before administering potassium by the intravenous route a non potassium containing hydrating solution should be administered to ensure adequate renal function.

Repeated measurements of plasma potassium are necessary to determine whether further infusions are necessary and to avoid the development of hyperkalaemia this is especially liable to occur in renal failure. Continuous ECG monitoring is desirable.

The label states: Rapid infusion may be harmful.
Do not use unless the solution is clear and free from particles.
Contains 13.5 mmol potassium (500ml)
Contains 27 mmol potassium (1000ml)

4.5. Interactions with other Medicinal Products and other Forms of Interaction

Care should be exercised in the concurrent administration of potassium containing intravenous solutions and potassium sparing diuretics.

ACE-inhibitors; cyclosporin care should be taken when administering to patines with digitalis therapy.

4.6. Pregnancy and Lactation

The use of potassium containing solutions 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

Adverse effects are usually due to hyperkalaemia and include listlessness, mental confusion, parasthesiae, weakness, hypertension, arrhythmias and sometimes cardiac arrest.
Thrombosis of the selected vein may occasionally occur.

4.9. Overdose

Symptoms of overdosage include hypertension, cardiac arrhythmias, heart block and Cardiac arrest. Treatment is to stop infusion immediately and if there is persistent acidosis, administer an intravenous infusion of sodium bicarbonate.
Hyperkalaemia may be reversed by the administration of calcium gluconate injection 10% with ECG monitoring.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Potassium chloride and sodium chloride provide essential ions to maintain the intracellular/extracellular milieu.

5.2. Pharmacokinetic Properties

Not applicable.

5.3. Pre-clinical 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

Incompatibilities have been demonstrated in potassium containing intravenous infusions with for example; amikacin, amphotericin, benzyl-penicillin and dobutamine.

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

6.3. Shelf-Life

500ml & 1000ml PVC bags - 24 months.
500ml & 1000ml Polyolefin bags - 36 months.

6.4. Special Precautions for Storage

Store at 2° to 25°C

6.5. Nature and Contents of Container

The container is a flexible 500 or 1000ml 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 500ml or 1000ml polyolefine bag sealed in a polyolefine overwrap.

6.6. Instruction for Use, Handling and 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.

7. MARKETING AUTHORISATION HOLDER

Fresenius Kabi Limited
Melbury Park,
Birchwood,
Warrington,
Cheshire
WA3 6FF

8. MARKETING AUTHORISATION NUMBER

PL 08828/0037

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

6TH June 1989 / 9th November 1994 / 20th March 2002

10. DATE OF (PARTIAL) REVISION OF THE TEXT

April 2000