SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.2%, Sodium Chloride 0.18%, Glucose 4% Solution for Infusion.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Chloride 0.2%, Sodium Chloride 0.18%, Glucose 4% Solution for Infusion has the following composition:

Name	Specification Reference	%w/v
Potassium Chloride	EP	0.2
Sodium Chloride for Injections	EP	0.18
Glucose Monohydrate for Parenteral Use	EP	4.4
(Equivalent to Anhydrous Glucose)		*4.0)*

For a full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Solution for 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 judgement of the physician.

Adults
The rate of infusion should not exceed 10-20 mmols of potassium per hour. The total daily dosage of potassium should not exceed 200 mmols 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 renal insufficiency.

Method of Administration

Solution for Infusion

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Solution for Infusion must be carried out slowly. Caution should be used with administration to patients receiving digitalis therapy, patients with renal or adrenal insufficiency, cardiac disease, acute dehydration, or heat cramp, those receiving potassium sparing diuretics and patients with sickle cell haemoglobinopathy.

Caution should be exercised in the volume and rate of infusion since fluid overload and hyperkalaemia may compromise 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 Interaction with other medicinal products and other forms of interaction

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

ACE-inhibitors; Cyclosporin; care should be taken when administering to patients with digitalis therapy.

4.6 Fertility, pregnancy and lactation

The safety of this product has not been assessed but its use in this period is not considered to constitute 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, hypotension, arrhythmias and sometimes cardiac
arrest.

Thrombosis of the selected vein may occasionally occur.

4.9 Overdose

Symptoms of overdosage include hypotension, cardiac arrhythmias, heart block and cardiac arrest. Treatment is to stop infusion immediately and if there is persistent acidosis, administer solution of 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.

Glucose is a monosaccharide, which provides a source of energy.

5.2 Pharmacokinetic properties

Glucose is metabolised via pyruvic or lactic acid to carbon dioxide and water with the release of energy. All body cells are capable of oxidising glucose and it forms the principal source of energy in cellular metabolism.

5.3 Preclinical safety data

Not Applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients.

Name
Water for Injection in Bulk
Hydrochloric Acid - for pH adjustment
Sodium Hydroxide - for pH adjustment

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 Steriflex 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

500 & 1000ml PVC Bags - 24 months
500 & 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 500 or 1000ml polyolefine bag sealed in a polyolefine overwrap.

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.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05.89/11.99/08.2001

10 DATE OF REVISION OF THE TEXT

27/01/2025