SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.2% and Glucose 5% Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Chloride 0.2% and Glucose 5% Solution for Infusion has the following composition:

Name	Specification Reference	%w/v
Potassium Chloride	EP	0.2
Glucose Monohydrate for Parenteral Use	EP	5.5
(Equivalent to Anhydrous Glucose		*5.0)*

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

Fluid balance, serum glucose, serum sodium and other electrolytes may need to be monitored before and during administration, especially in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs due to the risk of hyponatraemia.

Monitoring of serum sodium is particularly important for physiologically hypotonic fluids. Potassium Chloride 0.2% and Glucose 5% Solution for Infusion may become extremely hypotonic after administration due to glucose metabolization in the body (see sections 4.4, 4.5 and 4.8).

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

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

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 or chronic renal disease, oliguria, anuria and patients with hyperkalaemia.

Potassium Chloride and Glucose Solutions for Infusion may also be hazardous in, patients with impaired hepatic function.

4.4 Special warnings and precautions for use

Glucose solutions for infusion are usually isotonic solutions. In the body, however, glucose-containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization (see section 4.2).

Depending on the tonicity of the solution, the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize glucose, solution for infusion administration of glucose can cause electrolyte disturbances most importantly hypo- or hyperosmotic hyponatraemia.

Hyponatraemia:

Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns, and CNS diseases), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (brain oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients

with brain oedema are at particular risk of severe, irreversible and life-threatening brain injury.

Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, and cerebral contusion) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

Intravenous 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.

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

Drugs leading to an increased vasopressin effect. The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with Solution for Infusion (see sections 4.2, 4.4 and 4.8).

• Drugs stimulating vasopressin release, e.g.: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics

• Drugs potentiating vasopressin action, e.g.: Chlorpropamide, NSAIDs, cyclophosphamide

• Vasopressin analogues, e.g.: Desmopressin, oxytocin, vasopressin, terlipressin.

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.

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

4.6. Fertility, pregnancy and lactation

Potassium Chloride 0.2% and Glucose 5% Solution for Infusion should be administrated with special caution for pregnant women during labour particularly if

administered in combination with oxytocin due to the risk of hyponatraemia (see section 4.4, 4.5 and 4.8).

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, hypertension, arrhythmias and sometimes cardiac arrest.

Thrombosis of the selected vein may occasionally occur.

Tabulated list of adverse reactions		
System Organ Class	Adverse reaction (MedDRA term)	Frequency
Metabolism and nutrition disorders	Hospital Acquired Hyponatraemia**	Not known
Nervous system disorders	Hyponatraemic encephalopathy**	Not known

** Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2 and 4.4).

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

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.

Overdosage may lead to fluid overload and hyperglycaemia. Fluid overload may need to be treated with a diuretic and hyperglycaemia with insulin.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Potassium chloride provides essential ions to maintain the intracellular/extracellular milieu.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not Applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients.

Name	Specification Reference	%w/v
Water for Injection BP	EP	To 100
Hydrochloric Acid BP	EP	QS
Sodium Hydroxide BP	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 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

Fresenius Kabi Limited
Cestrian Court
Eastgate Way
Manor Park
Runcorn
Cheshire
WA7 1NT
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8. MARKETING AUTHORISATION NUMBER(S)

PL 08828/0027.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/08/2001

10 DATE OF REVISION OF THE TEXT

28/01/2025