SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v contains:

in 1 000 ml	
Potassium chloride	29.82 g
Sodium chloride	9.00 g
Electrolyte concentrations:	
Potassium	400 mmol/l
Sodium	154 mmol/l
Chloride	554 mmol/l

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion

A clear colourless aqueous solution

Theoretical osmolarity	1108 mOsmol/l
pH	4.5- 7.0

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v is used for the treatment of potassium depletion in patients for whom oral medication are inadequate

or in critical care settings (e.g. Intensive Care and High Dependency Units) in which patients are often fluid restricted and have regular measurement of serum potassium levels and continuous ECG monitoring.

Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v must be administered by slow intravenous infusion via a central venous route using an infusion pump.

4.2 Posology and method of administration

Posology

The dosage is dependent on age, weight and clinical condition of the patient, especially in patients with renal or cardiac insufficiency.

Dosage and rate of infusion should be determined by ECG and serum electrolyte monitoring. Adequate urine flow must be ensured.

Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v is particularly adapted for fluid restricted patients.

Adults

The following recommendations are general guidelines on potassium.

- Potassium

The amount required for correction of moderate potassium deficiency may be calculated according to the following formula:

mmol K^+required = (body weight [kg] × 0.2)* × 2 × (serum-K^+target** – serum-K^+actual [mmol/l])

*Term represents the extracellular fluid volume

** should be 4.5 mmol/l

The maximum recommended dose of potassium is 2 – 3 mmol/kg body weight (BW)/24 h.

Infusion rate

The infusion rate will depend on the conditions of the individual patient (see section 4.4).

Generally, the maximum potassium substitution rate is 20 mmol per hour.

In patients with chronic hyponatraemia the rate of infusion should be slow, so that the resulting increase of the serum sodium level is limited to a maximum of 0.35 mmol/l/h.

Duration of use

This medicinal product may be administered as long as there is an indication for potassium administration.

Maximum daily dose

The maximum recommended dose of potassium is 3 mmol/kg BW per 24 hours. In any case the limits for daily fluid intake must not be exceeded.

Paediatric population

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

Reduced volumes and rates of infusion may be required. Generally, a substitution rate of 0.5 mmol/kg BW per hour should not be exceeded.

Elderly patients

Basically, the same dosage as for adults applies, but caution should be exercised in patients suffering from further diseases like cardiac insufficiency or renal insufficiency that may frequently be associated with advanced age. See section 4.

Method of administration

Intravenous use.

Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v must be used only via a central venous route. Slow intravenous infusion at a rate normally not exceeding 20 mmol potassium per hour using an infusion pump.

In urgent cases where the serum potassium level is less than 2.0 mmol/l or where severe hypokalemia is a threat, rates up to 40 mmol per hour or 400 mmol over a 24 hour period can be administered very carefully when infused via a central vein to diminish the risk of causing sclerosis and when guided by continuous monitoring of the ECG and frequent serum K^+ determinations to avoid hyperkalemia and cardiac arrest. Ensure that the catheter is not in the atrium or ventricle to avoid localized hyperkalaemia.

As a matter of principle, infusion pumps should be used for the infusion of potassium in the setting of correction therapy.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Hyperkalaemia
- Hyperchloraemia
- Severe hypernatraemia
- Severe renal impairment with oliguria and anuria

4.4 Special warnings and precautions for use

Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v should only be administrated with caution in cases of:

- hypernatraemia
- disorders where restriction of sodium intake is indicated, such as cardiac insufficiency, generalized oedema, pulmonary oedema, hypertension, pre-eclampsia, severe renal insufficiency.
- Shock
- Extensive tissue destruction (e.g. burn injuries)
- hyperhydration

Care must be exercised in the administration of large volume infusion of solution to patients with oedematous states or pulmonary oedema.

Solutions containing potassium should be administered slowly and only after renal function has been established and proved adequate. In patients with renal impairment, its use must be carefully controlled by frequent determinations of plasma potassium concentrations and periodic ECGs. The infusion must be discontinued if signs of renal insufficiency develop during infusion.

Potassium supplements should be administered with caution in patients with cardiac disease particularly in digitalised patients (see section 4.5).

There are typical changes in the ECG when the potassium balance is disturbed (hypo- or hyperkalaemia). However, there is no linear relationship between the ECG changes and the concentration of potassium in the blood.

Sodium chloride supplementation must be exercised slowly in patients with chronic hyponatraemia as too rapid correction of serum sodium levels may in rare cases lead to osmotic side effects.

Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v is hypertonic. The administration of a substantially hypertonic solution may lead to a variety of

complications such as crenation (shrinkage) of red blood cells and general cellular dehydration. It should be administered with care in patients with hypertonic dehydration.

Special caution must be exercised if the solution is administered to acidotic patients as a decrease of serum pH (acidosis) is frequently accompanied by an increase in serum potassium.

Caution should be exercised when the solution is administered to patients with Addison's disease as these patients are predisposed to hyperkalaemia.

It must be made absolutely sure that the solution is administered intravenously, because paravenous administration may cause tissue necrosis.

Clinical supervision should include ECGs, regular checks of fluid balance and serum electrolytes.

Paediatric population

Premature or term infants may retain an excess of sodium due to immature renal function. In premature or term infants, repeated infusion of sodium chloride should therefore only be given after determination of the serum sodium level.

Elderly patients

Elderly patients, who are more likely to suffer from cardiac insufficiency and renal impairment, should be closely monitored during treatment, and the dosage should be carefully adjusted, in order to avoid cardio circulatory and renal complications resulting from fluid overload.

4.5 Interaction with other medicinal products and other forms of interaction

- **Digoxin, cardiac glycosides**

In patients under treatment with cardiac glycosides, care should be taken to keep the potassium concentration constant. In case of **hyperkalaemia** - the effect of cardiac glycosides may be weakened, and in case of **hypokalaemia** it may result in cardiac glycoside toxicity.

Interactions might occur in the concurrent administration of other antiarrhythmics.

- **Drugs with the potential to induce hyperkalaemia**

Care should be taken in the concurrent use of drugs containing potassium and other drugs with a potential to induce hyperkalaemia, such as:

- potassium-sparing diuretics such as spironolactone, triamterene
- ACE inhibitors
- AT_1-receptor antagonists
- non-steroidal anti-inflammatory agents
- cyclosporine. tacrolimus
- suxamethonium – aliskiren

The concomitant administration of potassium-containing solutions and these drugs may lead to severe hyperkalaemia, which may in turn lead to cardiac arrhythmia.

- **Drugs leading to a decrease of the serum potassium level**

ACTH, corticosteroids, amphotericin B and loop diuretics can increase the renal elimination of potassium.

- **Medicinal products causing sodium retention**

The concomitant use of sodium-retaining drugs (e.g. corticosteroids, non-steriodal anti-inflammatory agents) may lead to oedema.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v in pregnant women.

Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). However, as all components of Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v are naturally present in the body and their biochemical properties are well known, no toxic effects in relation to pregnancy are to be expected.

Caution should be exercised when prescribing this medicine to pregnant women. The products should be used only when clearly needed and after careful weighing out expected benefits against possible risks.

Caution should be exercised in the presence of pre-eclampsia (see section 4.4).

Breast-feeding

There are no or limited amount of data from the use of potassium chloride and sodium chloride in lactating women. However, as all components of this medicinal product are naturally present in the body and their biochemical properties are well known, no toxic effects in relation to lactation are to be expected.

Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v can be used during breastfeeding if clinically needed.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

Adverse reactions which may occur are related to the potassium content of the solution.

Listing of undesirable effects

The following convention has been used for the classification of undesirable effects in terms of frequency: very common (≥1/10), common (≥1/100 to < 1/10), uncommon (≥1/1,000 to < 1/100), rare (≥1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse events
Cardiac disorders	Not known	Too rapid infusion may provoke cardiac arrhythmias
General disorders and administration site conditions	Not known	Local reactions at the infusion site, including local pain, venous irritation and occasionally thrombophlebitis may occur

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 at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Symptoms

In case of overdose hyperkalaemia, hyperhydration, acid-base imbalances, oedema, particularly hypernatraemia, hyperchloraemia or potassium intoxication and electrolyte disorders can result.

The symptoms of hyperkalaemia are primarily cardiovascular disorders and include hypotension, cardiac arrhythmia, heart block, ECG abnormalities with development of biphasic curves and cardiac arrest. Other symptoms include paresthesias of extremities, muscle or respiratory paralysis, areflexia, weakness and mental confusion

Rapid increase of the serum sodium level in patients with chronic hyponatraemia may lead to the osmotic demyelination syndrome (see section 4.4).

Excessive administration of chloride may cause a loss of bicarbonate with an acidifying effect.

Treatment

Immediate interruption of the infusion, ECG monitoring, if necessary enhancement of urine flow and thus fluid and electrolyte excretion, administration of sodium bicarbonate and insulin. If insulin is given to increase cellular uptake of potassium, glucose should be given to avoid hypoglycaemia. In patients with persistent ECG abnormalities e.g. calcium gluconate may be administered to antagonise the cardiotoxic effects of potassium. Haemodialysis or peritoneal dialysis may be required in patients with renal insufficiency.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group

Solutions affecting the electrolyte balance

ATC code: B05B B01

Mechanism of action

Potassium is the major cation of intracellular fluid and is essential for maintenance of acid-base balance, isotonicity, and electrodynamic characteristics of the cell. The electrolyte is an important activator in many enzymatic reactions and is essential to a number of physiologic processes including transmission of nerve impulses,

contraction of cardiac, smooth, and skeletal muscles, gastric secretion, renal function, tissue synthesis, carbohydrate utilisation and protein synthesis.

Sodium is the major cation of the extracellular fluid and is principally responsible for the control of water distribution, fluid and electrolyte balance, and osmotic pressure of body fluids. Together with chloride and bicarbonate, sodium plays also an important role in the regulation of acid-base balance.

Chloride is the major extracellular anion; it closely follows the physiologic disposition of sodium and changes in the acid-base balance of the body are reflected by changes in serum chloride concentration.

Pharmacodynamic effects

In postoperative, posttraumatic and other clinical instances severe fluid and electrolyte losses are frequently observed and the above named physiologic functions are impaired. In these patients the application of the components contained in Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v is indicated to restore potassium levels and thus prevent further damage to the body.

5.2 Pharmacokinetic properties

Absorption

Since the ingredients of Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v are infused intravenously their bioavailability is 100 %.

Distribution

Infused potassium is actively transported into the cells, where its concentration is up to 40 times that outside the cell. Plasma potassium concentrations generally range from 3.5-5 mmol/l. Sodium and chloride mainly distribute in the extracellular space. Plasma sodium concentration is normally regulated at a concentration of 135-145 mmol/l and chloride at 98-108 mmol/l.

Biotransformation

Although sodium, potassium and chloride is absorbed, distributed and excreted, there is no metabolism in the strict sense.

The kidneys are the major regulator of the sodium and water balances. In co-operation with the hormonal control mechanisms (renin-angiotensin-aldosterone system, antidiuretic hormone) and the hypothetical natriuretic hormone they are primarily responsible for keeping the volume of the extracellular space constant and regulating its fluid composition. Factors influencing potassium transfer between intracellular and extracellular fluid such as acid-base disturbances can distort the relationship between plasma concentrations and total body stores. Chloride is exchanged for hydrogen carbonate in the tubule system and is, thus, involved in the regulation of the acid base balance.

Elimination

The kidneys are the main route of excretion for potassium, sodium, and chloride but small amounts are lost via the skin and intestinal tract. Especially surgery results in increased urinary excretion of potassium while water and sodium are retained. For supplementation it is essential to take into consideration that the homeostasis of the single electrolytes is influenced by the others and their regulation is thus interdependent to some degree.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

All components of Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v are naturally present in the body and their biochemical properties are well known. Therefore, toxic effects are not to be expected.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- water for injections
- hydrochloric acid, sodium hydroxide (for pH adjustment)

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

Unopened

- 50 ml plastic bags: 12 months
- 100 ml plastic bags: 20 months

After first opening the container

Not applicable. See 6.6.

After addition of additives

Not applicable. See 6.2.

6.4 Special precautions for storage

For 50 ml plastic bags: Store below 25°C.

For 100 ml plastic bags: This medicinal product does not require any special storage conditions.

Do not freeze.

For storage conditions of the medicinal product after addition of an additive, see section 6.3.

6.5 Nature and contents of container

Plastic bags Ecobag, content: 20 x 50 ml, 20 x 100 ml

The Ecobag is made of a PVC-free multi-layer co-extruded film. It is overwrapped with transparent multilayer plastic foil (from PA/PP or PP/PP).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Precautions for disposal

No special requirements for disposal.

Instructions for use and handling

Containers are for single use only. Discard container and any unused contents after use. Do not re-connect partially used containers.

Use only if the solution is clear, colourless and if the container is undamaged. The solution should not be administered if the container or its closure show visible signs of damage.

7 MARKETING AUTHORISATION HOLDER

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