Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Chloride 1.50 g/l Sodium Chloride 9.00 g/l

Each ml contains 1.50 mg potassium chloride and 9.00 mg sodium chloride.
Each 500 ml bottle contains 0.75 g potassium chloride and 4.5 g sodium chloride.
Each 1000 ml bottle contains 1.50 g potassium chloride and 9.00 g sodium chloride.

mmol/l: K^+: 20Na^+: 154 Cl^- : 174

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion
Clear and colourless solution, free from visible particles

Osmolarity: 348 mOsm/l (approx.)
pH: 4.5 – 7.0

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v is indicated for the prevention and treatment of potassium depletion and/or hypokalaemia, in sodium chloride and water-losing conditions.

4.2 Posology and method of administration

Doses may be expressed in terms of mEq or mmol of each cation, mass of each cation, or mass of each cation salt:
- for sodium

1 g NaCl = 394 mg of Na^+ or 17.1 mEq or 17.1 mmol of Na^+ and Cl^-
1 mmol Na^+ = 23 mg Na^+

- for potassium

1 g KCl = 525 mg of K^+ or 13.4 mEq or 13.4 mmol of K^+ and Cl^-
1 mmol K^+ = 39.1 mg K^+

The dosage of this solution depends on the age, weight, clinical and biological (acid-base balance) conditions of the patient, concomitant therapy and in particular the patient's hydration state.

General posology
The recommended dosage for treatment of isotonic fluid depletion (extracellular dehydration) by means of any intravenous solution is:
- for adults: 500 ml to 3 litres/24 h
- for babies and children: 20 to 100 ml per 24 h and per kg of body weight, depending of the age and the total body mass.

Posology
- Adults, Older people and Adolescents:

Typical dose of potassium for the prevention of hypokalaemia may be up to 50 mmol daily and similar doses may be adequate in mild potassium deficiency. When used for treatment of hypokelaemia, the recommended dosage is 20 mmol of potassium over 2 to 3 hours (i. e. 7-10 mmol/h) under ECG control.

- Paediatric population:
When used in the treatment of hypokalaemia the recommended dosage is 0.3 – 0.5 mmol/kg b.w./h. The dose has to be adjusted on frequently obtained lab values.
The maximal recommended dose of potassium is 2 to 3 mmol/kg b.w./day.

- Patients with renal impairment
Patients with renal impairment should receive lower doses.

Method of Administration
Route of administration
The administration is performed by intravenous route using sterile and non - pyrogenic equipment.

Intravenous potassium should be administered in a large peripheral or central vein to diminish the risk of causing sclerosis. If infused through central vein, be sure the catheter is not in the atrium or ventricle to avoid localized hyperkalaemia.

Solutions containing potassium should be administered slowly.

Rate of administration
As administered intravenously, potassium should not be given faster than 15 to 20 mmol/h to avoid a dangerous hyperkalaemia.

In any case, the dosage given under "General Posology" should not be exceeded.

Monitoring
Adequate urine flow must be ensured and careful monitoring of plasma-potassium and other electrolyte concentrations is essential. High dosage or high speed infusion must be performed under ECG control

4.3 Contraindications

- hyperkalaemia, hyperchloraemia or hypernatraemia
- severe renal insufficiency (with oliguria/anuria)
- uncompensated cardiac failure
- Addison's disease

4.4 Special warnings and precautions for use

Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v is a hypertonic solution, with an approximate osmolarity of 348 mOsm/l.

Administration should be carried out under regular and careful surveillance. Regular monitoring of clinical status, plasma electrolyte concentrations, plasma creatinine levels, BUN level, acid-base balance and ECG is essential in patients receiving potassium therapy, particularly those with cardiac or renal impairment.

Adequate urine flow should be ensured and fluid balance should be monitored.

Potassium salts should be administered with considerable care to patients with cardiac disease or conditions predisposing to hyperkalaemia such as renal or adrenocortical insufficiency, acute dehydration, or extensive tissue destruction as occurs with severe burns. In patients under digitalis therapy, regular monitoring of the plasma potassium level is mandatory.

Sodium salts should be administered with caution to patients with hypertension, heart failure, peripheral or pulmonary oedema, impaired renal function, pre-eclampsia, or other conditions associated with sodium retention (see also section 4.5).

4.5 Interaction with other medicinal products and other forms of interactions

Solutions containing potassium should be used with caution in patients receiving medicinal products that increase plasma potassium concentrations (e. g. potassium-sparing diuretics, ACE inhibitors, Angiotensin II receptors antagonists, ciclosporin, tacrolimus and medicinal products that contain potassium).

The pharmacological effect of digitalis glycosides (digoxin and methyldigoxin) and antiarrhythmic agents (such as quinidine, hydroquinidine, procainamide) can be altered as a function of blood potassium levels:
- Digitalis: hyperkalaemia reduces the therapeutic action of these drugs whereas hypokalaemia can cause digitalis toxicity.
- Antiarrhythmic agents: hyperkalaemia increases their antiarrhythmic effects and hypokalaemia reduces their efficacy.

Corticosteroids are associated with the retention of sodium and water, with oedema and hypertension.

4.6 Fertility, pregnancy and lactation

Hyperkalaemic and hypokalaemic serum levels lead to impaired cardiac function of the maternal and foetal hearts. Therefore, the maternal electrolyte levels are to be controlled regularly.

If taken for the corresponding indications and at the therapeutic dosage, administration of Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v would be possible during pregnancy and lactation.

This medicinal product contains sodium chloride. Therefore, extreme precautions should be taken if it is administered during pregnancy in situations of preeclampsia.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The following adverse reactions have been reported spontaneously during Post-Marketing use of the product. The frequencies cannot be estimated due to the nature of the data.

System Organ Class (SOC)	**MedDRA Preferred Term**
Infections and infestations	Injection site infection[(1)]
Metabolism and nutrition disorders	Hypervolemia[(1)]
General disorders and administration site conditions	Extravasation[(1)] Injection site irritation[(1)]) Injection site pain[(1)] Injection site phlebitis[(1)] Injection site reaction[(1)] Injection site thrombosis[(1)] Pyrexia[(1)]
[(1)]Adverse reactions that may be associated with the technique of administration	

In case of undesirable effect(s), the infusion must be discontinued

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Excessive administration of potassium may lead to the development of hyperkalaemia, especially in patients with renal impairment. Symptoms include paresthesia of the extremities, muscle weakness, paralysis, cardiac arrhythmias, heart block, cardiac arrest, and mental confusion. Among the important indicators of potassium toxicity are ECG changes, including tall, peaked T-waves, depression of S-T segment, disappearance of the P-wave, prolongation of the Q-T interval, and widening and slurring of the QRS complex.

Treatment of hyperkalaemia involves the administration of calcium, insulin or sodium bicarbonate, and exchange resins or dialysis.

Retention of excess sodium when there is a defective renal sodium excretion may result in pulmonary and peripheral oedema.

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

In the event of accidental over infusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the medicinal product administered. The relevant symptomatic and supportive measures should be provided as necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Blood substitutes and perfusion solutions; Electrolytes, ATC code: B05BB01

Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion is a hypertonic solution of electrolytes, with an approximate osmolarity of 348 mOsm/l.

The pharmacodynamic properties of the solution are those of the sodium, potassium and chloride ions in maintaining the fluid and electrolyte balance.

Potassium is essential for numerous metabolic and physiological processes including nerve conduction, muscle contraction, and acid-base regulation. A normal concentration of potassium in plasma is about 3.5 to 5.0 mmol per liter. Potassium is predominantly an intracellular cation. The passage of potassium into the cells and retention against the concentration gradient requires active transport via the Na^{+}/K^{+} ATPase enzyme.

Ions, such as sodium, circulate through the cell membrane, using various mechanisms of transport, among which is the sodium pump (Na-K-ATPase). Sodium plays an important role in neurotransmission and cardiac electrophysiology, and also in its renal metabolism.

Chloride is mainly an extracellular anion. Intracellular chloride is in high concentration in red blood cells and gastric mucosa. Reabsorption of chloride follows reabsorption of sodium.

5.2 Pharmacokinetic properties

The pharmacokinetic properties of Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v are those of the ions its composition includes (sodium, potassium and chloride).
Intravenous administration of the solution provides an immediate supply of electrolytes to blood.

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. Potassium is excreted mainly by the kidneys; it is secreted in the distal tubules in exchange of sodium or hydrogen ions. The capacity of the kidneys to conserve potassium is poor and some urinary excretion of potassium continues even when there is severe depletion. Some potassium is excreted in the feces and small amounts may also be excreted in sweat.

After injection of radiosodium (^{24}Na), the half-life is 11 to 13 days for 99 % of the injected Na and one year for the remaining 1 %. The distribution varies according to tissues: it is fast in muscles, liver, kidney, cartilage and skin; it is slow in erythrocytes and neurons; it is very slow in the bone. Sodium is predominantly excreted by the kidney, but there is extensive renal reabsorption. Small amounts of sodium are lost in the feces and sweat.

5.3 Preclinical safety data

Preclinical safety data of Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v in animals are not relevant since electrolytes are physiological components of the body.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections
Sodium hydroxide (for pH adjustment)

Hydrochloric acid (for pH adjustment)

6.2 Incompatibilities

Incompatibility of the medicinal product to be added to Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v must be assessed before addition.
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.
It is the responsibility of the doctor to judge the incompatibility of an additive medication towards the solution of Potassium Chloride 0.15 % w/v & Sodium Chloride 0.9 % w/v, by checking a possible change of colour and/or a possible formation of precipitate, insoluble complex or crystals. Refer also to the Summary of Product Characteristics accompanying the additive medicine.

The Instructions for Use of the medicinal product to be added must be consulted. Before adding a medicinal product, verify it is soluble and/or stable in water at the pH of Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v (pH: 4.5 to 7.0).

Those additives known to be incompatible should not be used**.**

6.3 Shelf life

30 months

In-use shelf life (Additives)
Chemical and physical stability of any additive medicinal product at the pH of the Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v should be established prior to use.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v is available in 500 ml and 1000 ml low-density polyethylene bottles as primary packaging closed with a polyolefin cap containing a polyisoprene rubber stopper. It is supplied in packs of 10 bottles.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v is a ready to use solution.
It is for single use only. Any unused solution should be discarded.

Use only if the solution is clear, without visible particles and if the container is undamaged.

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

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1
Bad Homburg v.d.H 61352
Germany

8 MARKETING AUTHORISATION NUMBER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd November 2014

10 DATE OF REVISION OF THE TEXT

April 2019 CRN008S1T