AUSTRALIAN PRODUCT INFORMATION

Potassium chloride 10 mmol in Sodium chloride 0.9% 500 mL injection for intravenous infusion

Potassium chloride 20 mmol in Sodium chloride 0.9% 500 mL injection for intravenous infusion

Potassium chloride 20 mmol in Sodium chloride 0.9% 1000 mL injection for intravenous infusion

Potassium chloride 40 mmol in Sodium chloride 0.9% 1000 mL injection for intravenous infusion

1 NAME OF THE MEDICINE

Potassium Chloride and Sodium Chloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bottle of Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion contains either 0.15% w/v (1.5 g/L, 20 mmol/L) or 0.3% w/v (3 g/L, 40 mmol/L) potassium chloride, as well as 0.9% w/v (9 g/L, 154 mmol/L) sodium chloride, as the active ingredients.

Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusions have a pH of 4.5–7.0 and osmolarity of 348 mOsm/L (0.15 % potassium chloride/0.9 % sodium chloride product) and 388 mOsm/L (0.3% potassium chloride/0.9% sodium chloride product). The 0.15 % w/v solution is isotonic and the 0.3% w/v solution is hypertonic.

For the full list of excipients, see Section 6.1 List of Excipients.

3 PHARMACEUTICAL FORM

Injection, intravenous infusion.

Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion is a clear colourless preservative free solution.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

A source of water and to restore electrolyte balance as required by a patient's clinical condition, such as hypokalaemia.

4.2 DOSE AND METHOD OF ADMINISTRATION

To be used as directed by the physician for intravenous use only. The choice of the specific Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion formulation, dosage, volume, rate and duration of administration is dependent upon the age, weight, clinical and biological (acid-base balance) condition of the patient, concomitant therapy and laboratory determinations. Additional electrolyte supplementation may be indicated according to the clinical needs of the patient. Administration should be determined by a physician experienced in intravenous fluid therapy. A rate-limiting device such as a rate-controlled infusion pump or burette should be used to prevent unintentional bolus doses of solutions containing potassium chloride. **Institutional guidelines for administration of intravenous potassium should be followed**. The need for ECG monitoring should be considered.

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

See **SECTION 2 QUALITATIVE AND QUANTITATIVE COMPOSITION** for the pH and osmolarity of Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusions. The osmolarity of a final admixed infusion solution must be taken into account when peripheral administration is considered. Hyperosmolar solutions may cause venous irritation and phlebitis. Thus, clinically significant hyperosmolar solutions are recommended to be administered through a large central vein, for rapid dilution of the hyperosmolar solution.

Solutions containing potassium should be administered under the following conditions:

- **the recommended administration rate in adults should not exceed 20 mmol/hour (*i.e.* 1.5 g KCl/hour) and not exceed 80 mmol for a 24-hour period (*i.e.* 6 g KCl/24 hour).**
- **paediatric use requires the application of specific institutional protocols to calculate appropriate dose rates for individual patients (in general the recommended dosage is 0.3- 0.5mmol/kg/hour). Do not exceed 3 mmol/kg/day (*i.e.* 0.22 g KCl/kg/day).**

Do not connect flexible plastic containers in series, in order to avoid air embolism due to possible residual air contained in the primary container.

Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion is intended for intravenous administration using sterile equipment and strict aseptic technique. Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration wherever solution and container permit. Do not administer unless solution is clear and seal is intact.

Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion contains no antimicrobial agents, and are for single use in only one patient. Unused portions must be discarded.

The volume in the 500 mL and 1000 mL bottles will accommodate additives. Do not add supplementary medication.

Check for leaks. If leaks are found, the container should be discarded, as sterility may be impaired.

Additives may be incompatible. When introducing additives to Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion, the instructions for use of the medication to be added and other relevant literature must be consulted. Before adding a substance or medication, verify that it is soluble and stable in Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion and that the pH range of the solution is appropriate. Only those additives known to be compatible can be added to these infusions. Consult with pharmacist, if available. If in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Add additives to the injection port using a 18–23 gauge (0.58–1.02 mm) needle, or using a transfer adapter. Carefully mix solution thoroughly. After addition, if there is a discoloration and/or the appearance of precipitates, insoluble complexes or crystals, do not use. Do not store solutions containing additives. Discard any unused portion. For single use in only one patient.

4.3 CONTRAINDICATIONS

- known hypersensitivity to any ingredients in the medicine
- documented hyperkalaemia, hyperchloraemia or hypernatraemia
- potassium retention
- congestive heart failure
- severe renal impairment
- acidosis
- haemolysis
- Addison's disease
- in conjunction with potassium-sparing diuretics
- clinical states in which the administration of sodium and chloride is detrimental.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Monitoring

Adequate urine flow must be ensured and careful monitoring of plasma potassium and other electrolyte concentrations is essential.

High dose or high speed infusion must be performed under continuous ECG monitoring.

Hypersensitivity Reactions

Hypersensitivity/infusion reactions including anaphylaxis have been reported with other products containing potassium chloride and sodium chloride. Stop the infusion immediately if signs or symptoms of hypersensitivity/infusion reactions develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Special Warnings

To avoid potassium intoxication, Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion must not be infused rapidly. 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.

When infusing Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion, care must be taken to prevent paravenous administration or extravasation because such solutions may be associated with tissue damage, which may be severe and include vascular, nerve and tendon damage, leading to surgical intervention, including amputation. Secondary complications including pulmonary embolism from thrombophlebitis have been reported as a consequence of tissue damage from potassium chloride.

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 Section 4.5 Interactions with Other Medicines and Other Forms of Interactions**).

Rapid correction of hypernatraemia and hyponatraemia is potentially dangerous (risk of serious neurological complications).

In order to reduce risks of thrombophlebitis, it is recommended to change the injection site every 24 hours.

In a dilute condition, osmolarity/L is approximately the same with osmolality/kg.

The addition of potassium chloride into an isotonic sodium chloride renders Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion to be hypertonic (**see SECTION 2 QUALITATIVE AND QUANTITATIVE COMPOSITION** for osmolarity of the medicines). Administration of a substantially hypertonic solution may lead to a wide variety of complications, such as crenation (shrinkage) of red blood cells and general cellular dehydration.

Risk of Hyperkalaemia

Potassium salts should be administered with considerable care to patients with cardiac disease or conditions predisposing to hyperkalaemia and/or associated with increased sensitivity to potassium such as patients with:

- renal impairment or adrenocorticol insufficiency
- acute dehydration
- extensive tissue injury or burns
- certain cardiac disorders such as congestive heart failure or AV block (especially if they receive digitalis). In patients under digitalis therapy, regular monitoring of the plasma potassium level is mandatory
- potassium-aggravated skeletal muscule channelopathies (e.g. hyperkalaemic periodic paralysis, paramyotonia congenita and potassium-aggravated myotonia/paramyotonia).

Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion should be administered with caution to patients who are at risk of experiencing hyperosmolality, acidosis or undergo correction of alkalosis (conditions associated with a shift of potassium from intracellular to extracellular space) and patients treated concurrently or recently with agents or products that can cause hyperkalaemia (see **Section 4.4 Special Warnings and Precautions for Use**). Close monitoring, careful dose selection and adjustment is required particularly in high risk patients.

Hyperkalaemia can cause cardiac conduction disorders (including complete heart block) and other cardiac arrhythmias at any time during infusion. Continuous ECG monitoring is performed to aid in the detection of cardiac arrhythmias due to a sudden increase in serum potassium concentration (e.g. when potassium infusion is started) or transient or sustained hyperkalaemia (see **Section 4.8 Adverse Effects** and **Section 4.9 Overdose**).

Frequently, mild or moderate hyperkalaemia is asymptomatic and may be manifested only by increased serum potassium concentrations and possibly characteristic ECG changes. However, fatal arrhythmias can develop at any time during hyperkalaemia. Serum potassium levels are not necessarily indicative of tissue potassium levels.

Use in Patients at Risk of Sodium Retention, Fluid Overload and Oedema

Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion should be used with particular caution, in patients with or at risk for:

- hypernatraemia
- hyperchloremia
- metabolic acidosis
- hypervolemia
- conditions that may cause sodium retention, fluid overload and oedema (central and pheripheral).

Risk of Serum Electrolytes and Water Imbalance

Depending on the volume and rate of infusion and depending on a patient's underlying clinical condition, the intravenous administration of Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous infusion can cause:

- fluid and/or solute overloading resulting in dilution of the serum electrolyte concentrations
- electrolyte disturbances such as:
  - hypernatraemia
  - hyponatraemia
- acid-base imbalance
- overhydration/hypervolemia, congested states including central (e.g. pulmonary congestion) and peripheral oedema.

The risk of dilution states is inversely proportional to the electrolyte concentrations of the injections.

The risk of solute overload causing congested states with peripheral and pulmonary oedema is directly proportional to the electrolyte concentrations of the injections.

Regarding medications that increase the risk of hyponatraemia or sodium and fluid retention, see **Section 4.5 Interactions with other Medicines and Other Forms of Interactions.**

In patients with diminished renal function, administration of Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion may result in sodium or potassium retention. Clinical evaluation and periodic laboratory determinations may be necessary to monitor changes in fluid balance, electrolyte concentration and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

Hyponatraemia

Monitoring of serum sodium is particularly important for hypotonic fluids (see section 2 Qualitative and Quantitative Composition, Table 1, for osmolarity of the solutions). High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatraemia.

Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion should be used with particular caution in patients with or at risk of hyponatraemia, for example:

- in children
- in elderly patients
- in women
- postoperatively
- in persons with psychogenic polydipsia
- in patients treated with medications that increase the risk of hyponatraemia (such as certain antiepileptic and psychotropic medications).

The risk for developing hyponatraemic encephalopathy is increased, for example:

- in paediatric patients (≤ 16 years of age)
- in women (in particular, premenopausal women)
- in patients with hypoxemia
- in patients with underlying central nervous system disease.

Hyponatraemia can lead to acute hyponatraemic encephalopathy (brain oedema) characterised by headache, nausea, seizures, lethargy and vomiting, coma, cerebral oedema, and death. Patients with brain oedema are at particular risk of severe, irreversible and life-threatening brain injury. Acute symptomatic hyponatraemic encephalopathy is considered a medical emergency.

Use in Patients at Risk of Severe Renal Impairment

Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion should be administered with particular caution to patients at risk of severe renal impairment. In such patients, administration of Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion may result in sodium retention, fluid overload, and/or may predispose to hyperkalaemia.

Risk of air embolism

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container.

Pressurising intravenous solutions contained in flexible containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Use in the elderly

When selecting the type of infusion solution and the volume/rate of infusion for a geriatric patient, consider that geriatric patients are generally more likely to have cardiac, renal, hepatic, and other diseases and/or concomitant drug therapy.

Paediatric use

These solutions have not been developed for use in children, and age specific paediatric protocols must be consulted.

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy, and should be determined by a physician experienced in paediatric intravenous fluid therapy. Paediatric use requires the application of specific institutional protocols to calculate appropriate dose rates for individual patients.

Children (including neonates and older children) are at increased risk of developing hyponatraemia, as well as for developing hyponatraemic encephalopathy. The infusion of Potassium Chloride and Sodium Chloride Intravenous Infusion together with the non-osmotic secretion of antidiuretic hormone may result in hyponatraemia.

Plasma electrolyte concentrations should be closely monitored in the paediatric population.

Effects on laboratory tests

The effect of this medicine on laboratory tests has not been established.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be increased during administration of Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion and this can result in decreased lithium levels.

Solutions containing potassium should be used with caution in patients treated concurrently or recently with agents or products that can cause hyperkalaemia or increase the risk of hyperkalaemia (e.g. potassium-sparing diuretics including amiloride, spironolactone and triamterene, ACE inhibitors, angiotensin II receptor antagonists, cyclosporin, tacrolimus and drugs that contain potassium such as potassium salts of penicillin). Administration of potassium in patients treated with such agents is associated with an increased risk of severe and potentially fatal hyperkalaemia particularly in the presence of other risk factors for hyperkalaemia.

Caution is advised when administering Potassium Chloride in Sodium Chloride Intravenous Infusion to patients treated with drugs leading to an increased vasopressin effect. The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hyponatraemia following treatment with IV fluids. (See section 4.4 Special Warnings and Precautions for Use and section 4.8 Adverse Effects (Undesirable Effects):

- Drugs stimulating vasopressin release such as chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors (SSRIs), 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsycotics, opioids.
- Drugs potentiating vasopressin action such as chlorpropamide, non-steroidal anti-inflammatories (NSAIDS), cyclophosphamide.
- Vasopressin analogues such as desmopressin, oxytocin, vasopressin, terlipressin

Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion should be used with particular caution in patients on concomitant medications that may increase the risk of sodium and fluid retention, such as corticosteroids. Corticosteroids and corticotropin are associated with the retention of sodium and water, with oedema and hypertension.

Potassium Chloride is not compatible with Mannitol 20%, Sodium Bicarbonate and Colloidal Solutions.

Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion should be administered with caution in patients on concomitant medications that increase the risk of hyponatraemia such as certain antiepileptic and psychotropic medications.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy – *Category C*

Animal reproduction studies have not been conducted with Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion. It is also not known whether these dosage forms can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity. There are no adequate data from the use of Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion in pregnant women. Physicians should carefully consider the potential risks and benefits for each specific patient before administering Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion.

Use in lactation

Safety in lactation has not been established. There are no adequate data from the use of Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion in lactating women. Physicians should carefully consider the potential risks and benefits for each specific patient before administering Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Adverse reactions to potassium containing solutions include hyperkalaemia, paraesthesia of the extremities, flaccid paralysis, mental confusion, hypotension, cardiac arrhythmias, heart block, ECG abnormalities and cardiac arrest.

Adverse reactions which may occur because of the solution or the technique of administration, include fever response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia. If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Post-Marketing Experience

The following adverse reactions have been reported in the post-marketing experience listed by MedDRA System Organ Class (SOC).

IMMUNE SYSTEM DISORDERS
Hypersensitivity, as manifested by rash and angioedema

METABOLISM AND NUTRITION DISORDER
Hyperkalaemia, hyponatraemia, hypernatraemia, acidosis hyperchloremic, fluid overload

CARDIAC DISORDERS
Cardiac arrest*, asystole*, ventricular fibrillation*, bradycardia (*as manifestation of rapid intravenous administration and/or of hyperkalaemia)

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS
Dyspnoea

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS

Chest pain, chills, infusion site pain, infusion site irritation, burning sensation.

Other adverse reaction associated with administration of potassium chloride in sodium chloride intravenous infusions include:

- in association with extravasation: skin necrosis, skin ulcer, soft tissue necrosis, muscle necrosis, nerve injury, tendon injury and vascular injury;
- infusion site thrombosis, infusion site phlebitis, infusion site swelling and infusion site erythema.

Other reactions (Class reactions)

Other adverse reactions reported with other similar products include:

• NERVOUS SYSTEM DISORDERS: hyponatraemic encephalopathy

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Excess administration of Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion can cause:

- hyponatraemia (which can lead to CNS manifestations including seizures, coma, cerebral edema and death);
- hypernatraemia, especially in patients with severe renal impairment;
- hyperkalaemia.

Potassium overdose can cause potentially fatal hyperkalaemia. The clinical signs and symptoms of hyperkalaemia include:

- disturbances in cardiac conduction and arrhythmias, including bradycardia, heart block, asystole, ventricular tachycardia, ventricular fibrilliation;
- hypotension, cold skin, grey pallor and peripheral collapse with fall in blood pressure;
- muscle weakness up to and including muscular and respiratory paralysis, paraesthesia of extremities;
- gastrointestinal symptoms (ileus, nausea, vomiting, abdominal pain);
- mental confusion;
- fluid overload (which can lead to central and/or peripheral oedema). (see section 4.4 Special Warnings and Precautions for Use and section 4.8 Adverse effects (Undesirable effects))

Extremely high serum potassium concentrations (8–11 mmol/L) may cause death from cardiac depression, arrhythmias or arrest.

Frequently, mild or moderate hyperkalaemia is asymptomatic and may be manifested only by increased serum potassium concentrations and, possibly, characteristic electrocardiographic changes. However, fatal arrhythmias can develop at any time.

In addition to arrhythmias and conduction disorders, the ECG shows progressive changes that occur with increasing potassium levels. Possible changes include:

- peaking of T waves;
- loss of P waves; and
- QRS widening.

The presence of any ECG findings that are suspected to be caused by hyperkalaemia should be considered a medical emergency.

When assessing an overdose, any additives in the solution must also be considered. The effects of an overdose may require immediate medical attention and treatment. Interventions include discontinuation of administration of Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion, dose reduction and other measures as indicated for the specific clinical constellation.

If hyperkalaemia is present or suspected, discontinue the infusion immediately and institute close ECG, laboratory and other monitoring and, as necessary, corrective therapy to reduce serum potassium levels.

Lowering of the potassium level should be approached with thorough consideration on adverse effects that may occur, in particular with digitalised patients.

A state of hypokalaemia increases the risk of digitalis toxicity. Plasma electrolyte abnormalities (hypomagnesemia, hypokalaemia and metabolic alkalosis) also contribute to the clinical toxicity even at normal digoxin plasma level. Thus, caution should be exercised when lowering the potassium level in a digitalised patient.

Contact the Poisons Information Centre on 13 11 26 for advice on management of overdosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion is mainly intended for the treatment of potassium depletion. Thus, the mode of action of these formulations should be looked at from that viewpoint. Potassium is a major cation of the intracellular fluid (160 mmol/L of intracellular water) found primarily in muscle cells. It functions principally in the maintenance of acid-base balance; isotonicity and electrodynamic characteristics of the cells. In contrast, sodium is the major cation of the extracellular fluid (135–145 mmol/L) and functions principally in the control of water distribution, fluid and electrolyte balance and osmotic pressure of body fluids.

Na-K-ATPase membrane-bound enzymes regulate the passage of potassium against a higher potassium concentration in the cells. Potassium participates in carbohydrate utilisation, protein synthesis, and is critical in the regulation of nerve conduction and muscle contraction, particularly in the cardiac muscle.

Chloride, the major extracellular anion, closely follows the physiological disposition of sodium cation in maintenance of acid-base balance, isotonicity and electrodynamic characteristics of the cells. An increase of chloride concentration may result in a decrease of bicarbonate level, which leads to plasma acidosis, as shown by the charge-neutrality of the cells by the following equation. That is, $Na+ = Cl– + HCO_3– +$ [anion gap]-, where pH is related to equation, $pH = pKH_2CO_3 + \log [HCO_3]/[H_2CO_3]$. The anion gap is called "unmeasured anion", thus, Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion has a value as a source of water and electrolytes where kidneys may excrete potassium up to 80–90 mmol daily.

Daily requirements of potassium are between 0.8–1.2 g.

Clinical trials

No data available

5.2 PHARMACOKINETIC PROPERTIES

Absorption

As Fresenius Kabi's Potassium Chloride in Sodium Chloride Intravenous Infusion is directly administered to the systemic circulation, the bioavailability (absorption) of the active components is complete (100 %).

Distribution

From the vascular system, potassium ions first enter the extracellular/interstitial fluid, which then are pumped into the cells against concentration gradient by the Na-K-ATPase active transport mechanism.

Metabolism and Excretion

The level of potassium in the body is regulated by glomerular filtration and distal tubular secretion. Potassium excretion site is accompanied by sodium and water reabsorption back into systemic circulation. Thus, the kidney constantly adjusts the sodium and potassium level through this mechanism. The loss of sodium can be reduced to zero by increasing potassium and hydrogen ion excretion. Hormones, antidiuretic hormone and aldosterone control the kidney function in reabsorption of water and excretion of potassium, respectively.

The capacity of the kidney to conserve potassium is poor and some urinary excretion of potassium continues even when there is severe depletion. Some potassium is excreted in the faeces and small amounts may be excreted in sweat.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

The active ingredients are not mutagenic

Carcinogenicity

The active ingredients are not carcinogenic.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for Injections and hydrochloric acid and/or sodium hydroxide.

6.2 INCOMPATIBILITIES

Potassium chloride is not compatible with Mannitol 20 %, Sodium Bicarbonate and Colloidal solutions.

Care should be exercised regarding a possible incompatibility outcome resulting either from the interaction between the bottle or active ingredients and added therapeutic substances.

The introduction of additives to any solution, regardless of type of container, requires special attention to ensure that no incompatibilities result. While some incompatibilities are readily observed, one must be aware that subtle physical, chemical and pharmacological incompatibilities can occur. The medical literature, the package insert and other available sources of information should be reviewed for thorough understanding of possible incompatibility problems. Additives known or determined to be incompatible should not be used.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Do not freeze.

Store in the original container.

6.5 NATURE AND CONTENTS OF CONTAINER

Potassium chloride 10 mmol in Sodium chloride 0.9 % 500 mL injection for intravenous infusion (AUSTR 296132).

Potassium chloride 20 mmol in Sodium chloride 0.9 % 500 mL injection for intravenous infusion (AUST R 296133).

Potassium chloride 20 mmol in Sodium chloride 0.9 % 1000 mL injection for intravenous infusion (AUSTR 296131).

Potassium chloride 40 mmol in Sodium chloride 0.9 % 1000 mL injection for intravenous infusion (AUST R 296130).

Each product above is supplied as a single unit dose in Polyethylene bottle (as the primary packaging) with a polyethylene or polypropylene cap and polyisoprene stopper (KabiPac®).

Each bottle (all strengths above, in either 500 mL or 1000 mL) is packaged within a carton, each carton contains either 1 or 10 bottles.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Potassium chloride and sodium chloride occur as colourless or white crystals and are freely soluble in water.

Chemical structure

Chemical Name: Potassium chloride
Chemical Structure: K—Cl
Molecular Formula: KCl
Molecular Weight: 74.55

Chemical Name: Sodium chloride
Chemical Structure: Na—Cl
Molecular Formula: NaCl
Molecular Weight: 58.44

CAS number

Potassium Chloride: 7447-40-7

Sodium Chloride: 7647-14-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

Australia: Not scheduled

New Zealand: Not scheduled

8 SPONSOR

Fresenius Kabi Australia Pty Limited

Level 2, 2 Woodland Way

Mount Kuring-Gai NSW 2080

Telephone: (02) 9391 5555

Fresenius Kabi New Zealand Limited

60 Pavilion Drive

Airport Oaks, Auckland 2022

New Zealand

Freecall: 0800 144 892

9 DATE OF FIRST APPROVAL

18th January 2019

10 DATE OF REVISION

21 April 2021

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	New Format
4.4, 4.5, 4.8	Safety related changes