

NEW ZEALAND DATA SHEET

1 Potassium Chloride and Sodium Chloride (infusion, solution)

Potassium Chloride 10mmol in 0.29% Sodium Chloride (100mL)

Potassium Chloride 20mmol in 0.9% Sodium Chloride (1000mL)

Potassium Chloride 30mmol in 0.9% Sodium Chloride (1000mL)

Potassium Chloride 40mmol in 0.9% Sodium Chloride (1000mL)

Potassium Chloride 40mmol in 0.9% Sodium Chloride (100mL)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients

Potassium chloride and Sodium chloride.

The concentrations of the active ingredients and excipients are as follows:

Potassium Chloride 10mmol in 0.29% Sodium Chloride (100mL) (Potassium Chloride 10mmol (7.5g/L) infusion solution, BP in 100mL).

Potassium Chloride 20mmol in 0.9% Sodium Chloride (1000mL) (Potassium Chloride 20mmol (0.15%) and 0.9% Sodium Chloride infusion solution, BP in 1000mL).

Potassium Chloride 30mmol in 0.9% Sodium Chloride (1000mL) (Potassium Chloride 30mmol (0.224%) and 0.9% Sodium Chloride infusion solution, BP in 1000mL).

Potassium Chloride 40mmol in 0.9% Sodium Chloride (1000mL) (Potassium Chloride 40mmol (2.98g/L) infusion solution, BP in 1000mL).

Potassium Chloride 40mmol in 0.9% Sodium Chloride (100mL) (Potassium Chloride 40mmol (29.8g/L) and 0.9% (9g/L) Sodium Chloride infusion solution, BP in 100mL).

The amounts of potassium chloride and sodium chloride, dissolved in Water for Injection, are also tabulated in section 6.1.

Potassium Chloride and Sodium Chloride infusion solutions do not contain an antimicrobial agent or an added buffer.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.

Potassium Chloride and Sodium Chloride infusions are sterile, non-pyrogenic solutions. They are clear, colourless solutions for intravenous infusion. They have a pH of 4.0 – 7.0.

The following products are isotonic solutions:

- **Potassium Chloride 10mmol in 0.29% Sodium Chloride (100mL)**
- **Potassium Chloride 20mmol in 0.9% Sodium Chloride (1000mL)**

The following products are hypertonic solutions:

- **Potassium Chloride 30 mmol in 0.9% Sodium Chloride (1000mL)**
- **Potassium Chloride 40 mmol in 0.9% Sodium Chloride (1000mL)**
- **Potassium Chloride 40 mmol in 0.9% Sodium Chloride (100mL).**

Osmolarities are listed in the following table.

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Potassium Chloride and Glucose infusion solution preparations	
Product name and quantity of the active components	Osmolarity Φ (mOsmol/L)
Potassium Chloride 10mmol (0.75%) in 0.29% (5mmol) Sodium Chloride (100mL)	300 (300)
Potassium Chloride 20mmol (0.15%) in 0.9% (154mmol) Sodium Chloride (1000mL)	348 (348)
Potassium Chloride 30mmol (0.224%) in 0.9% (154mmol) Sodium Chloride (1000mL)	368 (368)
Potassium Chloride 40mmol (0.298%) in 0.9% (154mmol) Sodium Chloride (1000mL)	388 (388)
Potassium Chloride 40mmol (2.98%) in 0.9% (154mmol) Sodium Chloride (100mL)	1100 (1100)
Note: Potassium Chloride 40mmol/100mL is significantly hypertonic. Osmolarity Φ is a calculated figure. In dilute conditions osmolarity/L is approximately the same as osmolality/kg. The figures in the brackets are approximately Osmolality (mOsmol/kg).	

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Potassium Chloride and Sodium Chloride infusion solutions are indicated as a source of water and to restore electrolyte balance as required by the 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 **Potassium Chloride and Sodium Chloride** infusion solutions 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 should be used to prevent unintentional bolus doses of solutions containing potassium chloride. **Institutional guidelines for administration of intravenous potassium should be followed.**

Intravenous potassium should be administered in 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. The **Potassium Chloride and Sodium Chloride** infusion solutions range have a pH of 4.0 - 7.0 and their osmolarity are listed in the table in section 6.1. 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.

The following intravenous potassium infusion solutions should be administered in 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.

- **Potassium Chloride 10mmol and 0.29% Sodium Chloride in 100mL**
- **Potassium Chloride 20mmol and 0.9% Sodium Chloride in 1000mL**
- **Potassium Chloride 30mmol and 0.9% Sodium Chloride in 1000mL**
- **Potassium Chloride 40mmol and 0.9% Sodium Chloride in 1000mL.**

Solutions containing potassium should be administered under the following conditions:

- The 100mL presentation must be infused over at least 1 hr.
- **Potassium Chloride 40mmol and 0.9% Sodium Chloride in 100mL** must be administered via a central line (see section 4.8) to diminish the risk of causing sclerosis. Be sure the catheter is not in the atrium or ventricle to avoid localised hyperkalaemia.

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- The maximum time over which infusion may occur is 12 hours for the 100mL product, and 24 hours for the 1000mL presentations.
- The recommended administration rate should not exceed 20mmol/hour and not exceed 80mmol for a 24-hour period (= 6g KCl/24hr).
- Paediatric use requires the application of specific institutional protocols to calculate appropriate dose rates for individual patients. Do not exceed 3mmol/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.

Potassium Chloride and Sodium Chloride infusion solutions are intended for intravenous administration using sterile and strict aseptic technique. Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration wherever solution and container permit (see section 4.4). Do not administer unless solution is clear and seal is intact.

The solutions contain no antimicrobial agents, and are for single use in only one patient. Unused portions must be discarded.

The volume in the 1000mL bags will accommodate additives. The volume in the 100mL bags, will NOT accommodate additives. Do not add supplementary medication. See section 6.2.

Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be impaired.

Additives may be incompatible (see section 6.2). When introducing additives to **Potassium Chloride and Sodium Chloride** infusion solutions, 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 **Potassium Chloride and Sodium Chloride** infusion solutions, 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 inverted container (ports uppermost) with a 0.63 – 0.80mm needle. Squeeze ports and mix thoroughly. After addition, if there is a discoloration and/or the appearance of precipitates, insoluble complexes or crystals, do not use.

In case of damage, the container should be discarded. Do not store solutions containing additives.

Monitoring

Adequate urine flow must be ensured and careful monitoring of electrolyte concentrations and ECG is essential (see section 4.4).

4.3 Contraindications

The **Potassium Chloride and Sodium Chloride** infusion solutions are contraindicated in patients with:

- Known hypersensitivity to the product or to any of the excipients listed in section 6.1.
- Documented hyperkalaemia, hyperchloraemia or hypernatraemia.
- Potassium retention.
- Congestive heart failure.
- severe impairment of renal function.
- Acidosis.
- Haemolysis.

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- 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

Special warnings

High dose or high-speed infusion must be performed under continuous ECG monitoring. To avoid potassium intoxication, **Potassium Chloride and Sodium Chloride** infusion solutions 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 **Potassium Chloride and Sodium Chloride** infusion solutions; 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 also section 4.5).

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

To reduce risks of thrombophlebitis, it is recommended to change the injection site every 24hrs.

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

The addition of potassium chloride into an isotonic sodium chloride renders the **Potassium Chloride and Sodium Chloride** infusion solution to be hypertonic (see section 6.5). Administration of substantially hypertonic solutions may lead to a wide variety of complications, such as crenation (shrinkage) of red blood cells and general cellular dehydration.

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.

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 adrenocortical insufficiency.
- Acute dehydration.
- Extensive tissue injury or burns.

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- 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 muscle channelopathies (e.g., hyperkalaemic periodic paralysis, paramyotonia congenita, and potassium-aggravated myotonia/paramyotonia).

Potassium Chloride and Sodium Chloride infusion solution 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 4.5). 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 sections 4.8 4.9).

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

Potassium Chloride and Sodium Chloride infusion solution 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 peripheral).

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 the **Potassium Chloride and Sodium Chloride** infusion solution 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.

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In patients with diminished renal function, administration of **Potassium Chloride and Sodium Chloride** infusion solution 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 6.1, 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.

Potassium Chloride and Sodium Chloride infusion solution 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 which may lead to coma 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 several renal impairment

Potassium Chloride and Sodium Chloride infusion solution should be administered with particular caution to patients at risk of severe renal impairment. In such patients, administration of **Potassium Chloride and Sodium Chloride** infusion solution 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.

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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 medicinal 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 depend 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** infusion solution together with the non-osmotic secretion of ADH 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 Interaction with other medicines and other forms of interaction

Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be increased during administration of **Potassium Chloride and Sodium Chloride** infusion solutions 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 medicines 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 and Sodium Chloride** infusion solutions to patients treated with medications leading to an increased vasopressin effect. The below listed medicines 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 sections 4.4 & 4.8):

- Medications stimulating vasopressin release such as chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors (SSRIs), 3,4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, opioids.
- Medications potentiating vasopressin action such as chlorpropamide, non-steroidal anti-inflammatories (NSAIDs), cyclophosphamide.
- Vasopressin analogues such as desmopressin, oxytocin, vasopressin, terlipressin.

Potassium Chloride and Sodium Chloride infusion solution should be used with particular caution in patients on concomitant medications that may increase the risk of sodium and fluid retention, such

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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.

Potassium Chloride and Sodium Chloride infusion solutions should be administered with caution in patients on concomitant medications that increase the risk of hyponatraemia such as certain diuretics, and certain antiepileptic and psychotropic medications.

The safety of the Vialflex plastic container used to contain **Potassium Chloride and Sodium Chloride** infusion solutions has been confirmed in tests in animals according to the USP biological tests for plastic containers, as well as by tissue culture toxicity studies. Nevertheless, care should be exercised regarding a possible incompatibility outcome resulting either from the interaction between the plastic container or active ingredients and the added therapeutic substances (see section 4.2).

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, data sheet, 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. See section 6.2.

4.6 Fertility, pregnancy and lactation

Fertility

No data available.

Pregnancy (Category C)

Animal reproduction studies have not been conducted **Potassium Chloride and Sodium Chloride** infusion solutions. It is 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 **Potassium Chloride and Sodium Chloride** infusion solutions in pregnant women. Physicians should carefully consider the potential risks and benefits for each specific patient before administering **Potassium Chloride and Sodium Chloride** infusion solutions.

Breast-feeding

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

4.7 Effects on ability to drive and use machines

There is no information on the effects of **Potassium Chloride and Sodium Chloride** infusion solutions on the ability to operate an automobile or other heavy machinery.

4.8 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.

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Adverse reactions which may occur because of the solution or the technique of administration, including 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

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 hyperchloroemic, 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 and Sodium Chloride** infusion solutions 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 of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continuing monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphv.otago.ac.nz/reporting/>

4.9 Overdose

Excessive administration of **Potassium Chloride and Sodium Chloride** infusion solutions can cause:

- Hyponatraemia (which can lead to CNS manifestations including seizures, coma, cerebral oedema 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 fibrillation
 - 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 (ilues, nausea, vomiting, abdominal pain)
 - mental confusion.
- fluid overload (which can lead to central and/or peripheral oedema).

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

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Frequently, mild or moderate hyperkalemia 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 **Potassium Chloride and Sodium Chloride** infusion solution administration, 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.

For advice on the management of overdose please contact the National Poisons Centre on phone number: 0800 764 766 [0800 POISON] in New Zealand (or 131126 in Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group

Blood substitutes and perfusion solutions, IV solution additives, electrolyte solutions.

ATC code

B05XA01 (potassium chloride)

B05XA03 (sodium chloride).

Mechanism of action

Potassium Chloride and Sodium Chloride infusion solutions are 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 the major cation of intracellular fluid (approximately 160mmol/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 – 145mmol/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

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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:

$$\text{That is:} \quad \text{Na}^+ = \text{Cl}^- + \text{HCO}_3^- + [\text{anion gap}]^-$$

$$\text{where pH is related to equation:} \quad \text{pH} = \text{pK}_{\text{H}_2\text{CO}_3} + \log [\text{HCO}_3^-]/[\text{H}_2\text{CO}_3]$$

The anion gap is called "unmeasured anion", thus, **Potassium Chloride and Sodium Chloride** infusion solutions have value as a source of water, and electrolytes where the kidney may excrete potassium up to 80 – 90mmol daily.

Daily requirements of potassium are between 800mg to 1.2g.

Physiochemical properties potassium chloride

<i>Molecular formula</i>	KCl
<i>Molecular weight</i>	74.55
<i>Appearance</i>	Colourless or white crystal
<i>Solubility</i>	Freely soluble in water
<i>CAS</i>	7447-40-7

Physiochemical properties sodium chloride

<i>Molecular formula</i>	NaCl
<i>Molecular weight</i>	58.44
<i>Appearance</i>	Colourless or white crystal
<i>Solubility</i>	Freely soluble in water and practically insoluble in anhydrous ethanol
<i>CAS</i>	7647-14-5

5.2 Pharmacokinetic properties

As the **Potassium Chloride and Sodium Chloride** infusion solutions are directly administered to the systemic circulation, the bioavailability (absorption) of the active components is complete (100%). 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.

The level of potassium in the body is regulated by glomerular filtration and distal tubular secretion. Potassium excretion 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, ADH (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 ions 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.

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5.3 Preclinical safety data

Genotoxicity

The active ingredients, potassium chloride and sodium chloride are not mutagenic.

Carcinogenicity

The active ingredients, potassium chloride and sodium chloride are not carcinogenic.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

Hydrochloric acid (for pH adjustment).

6.2 Incompatibilities

Additives may be incompatible (see section 4.2). Consult with a pharmacist, if available. Check additive compatibility with both the solution and container prior to use. Those additives known or determined to be incompatible should not be used (see sections 4.2 and 4.5).

6.3 Shelf life

Potassium Chloride 10mmol in 0.29% Sodium Chloride (100mL): 9 months from date of manufacture.

Potassium Chloride 20mmol in 0.9% Sodium Chloride (1000mL): 24 months from date of manufacture.

Potassium Chloride 30mmol in 0.9% Sodium Chloride (1000mL): 24 months from date of manufacture.

Potassium Chloride 40mmol in 0.9% Sodium Chloride (1000mL): 12 months from date of manufacture.

Potassium Chloride 40mmol in 0.9% Sodium Chloride (100mL): 24 months from date of manufacture.

The expiry date can be found on the packaging.

6.4 Special precautions for storage

Store at or below 30°C. Do not freeze.

Exposure to heat should be minimised. Avoid excessive heat.

6.5 Nature and contents of container

Potassium Chloride and Sodium Chloride intravenous infusions are supplied in Viaflex plastic containers as a single unit dose. They are available in various strengths and pack sizes:

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Potassium Chloride and Sodium Chloride (IV) infusion solutions			
Item Code*	Trade Name of the active components & concentrations % (mmol/container)	TT50-	Pack size (mL)
AHB6008	Potassium Chloride 10mmol (0.75%, 7.5g/L) in 0.29% (2.9g/L, 5mmol) Sodium Chloride (100mL)	7541	100 (x48)
AHB1764	Potassium Chloride 20mmol (0.15%, 1.5g/L) in 0.9% (9g/L, 154mmol) Sodium Chloride (1000mL)	2184/18	1000 (x12)
AHB1274	Potassium Chloride 30mmol (0.224%, 2.24g/L) in 0.9% (9g/L, 154mmol) Sodium Chloride (1000mL)	5538	1000 (x12)
AHB6034	Potassium Chloride 40mmol (0.298%, 2.98g/L) in 0.9% (9g/L, 154mmol) Sodium Chloride (1000mL)	7542	1000 (x1)
AHB6053	Potassium Chloride 40mmol (2.98%, 29.8g/L) in 0.9% (9g/L, 154mmol) Sodium Chloride (100mL)	7542/1	100 (x48)
Note: AHB6053 (40mmol/100mL) is significantly hypertonic. *Not all packs may be marketed.			

6.6 Special precautions for disposal

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

7 MEDICINE SCHEDULE

General Sale Medicine.

8 SPONSOR

Potassium Chloride and Sodium Chloride intravenous infusions are distributed in New Zealand by:

Baxter Healthcare Ltd
 33 Vestey Drive
 Mt Wellington
 Auckland 1060.

Baxter Healthcare Ltd
 PO Box 14 062
 Panmure
 Auckland 1741

Phone (09) 574 2400.

Potassium Chloride and Sodium Chloride intravenous infusions are distributed in Australia by:

Baxter Healthcare Pty Ltd
 1 Baxter Drive
 Old Toongabbie, NSW 2146.

9 DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine:

Potassium Chloride 10mmol in 0.29% Sodium Chloride (100mL): 7 June 2012.

Potassium Chloride 20mmol in 0.9% Sodium Chloride (1000mL): 29 September 1980.

Potassium Chloride 30mmol in 0.9% Sodium Chloride (1000mL): 29 September 1980.

Potassium Chloride 40mmol in 0.9% Sodium Chloride (1000mL): 7 June 2012.

Potassium Chloride 40mmol in 0.9% Sodium Chloride (100mL): 23 October 2014.

10 DATE OF REVISION OF THE TEXT

14 November 2019.

NEW ZEALAND DATA SHEET

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All	Editorial changes: formatting, spacing, capitalisation, bullet points, headings, made consistent throughout, and consistent with other Data Sheets in the Baxter product range. Information relocated throughout to more appropriate location, repeated information deleted.
3	Osmolarity table included in this section.
4.2	Safety information relating to introduction of additives moved from 6.2.
4.4	Safety information added relating to hyponatraemia.
4.5	Safety information added relating to vasopressin effect.
4.8	Safety information added relating to nervous system disorders.
5.1	Physiochemical properties included.
6.1	Information simplified by removing repeated information.

Based on Australian PI most recent amendment 20 May 2019, and CCSI44120180628.

Please refer to the Medsafe website (www.medsafe.govt.nz) for most recent data sheet.

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