POTASSIUM CHLORIDE 22.3%

(potassium chloride) 2.23 g in 10 mL Concentrated Injection for Infusion

THIS IS A CONCENTRATED SOLUTION AND MAY BE DANGEROUS IF USED UNDILUTED.

DILUTE BEFORE ADMINISTRATION

1 NAME OF THE MEDICINE

Potassium chloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Chloride 22.3% Concentrated Injection contains 2.23 g of potassium chloride. Each Potassium Chloride 22.3% Concentrated Injection vial contains 30 mmol potassium ions and 30 mmol chloride ions in 10 mL.

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

3 PHARMACEUTICAL FORM

Potassium Chloride 22.3% Concentrated Injection is a clear colourless sterile solution.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Potassium Chloride 22.3% Concentrated Injection is indicated for the treatment of potassium depletion in patients with hypokalaemia and treatment of digitalis intoxication. IV administration is indicated when the patient is unable to take potassium orally or if hypokalaemia is severe.

4.2 DOSE AND METHOD OF ADMINISTRATION

Potassium Chloride 22.3% Concentrated Injection is a concentrated solution and must be diluted before use.

Potassium Chloride 22.3% Concentrated Injection is administered intravenously only after dilution in a large volume parenteral fluid. The dose and rate of injection are dependent upon the individual patient's condition. The usual maximum concentration is 40 mmol/L.

In patients whose serum potassium concentration is above 2.5 mmol/L, the rate of infusion should not exceed 10 mmol/hour. The total dose should not exceed 200 mmol/24 hours.

If urgent treatment is required (serum potassium concentration less than 2 mmol/L with ECG changes or paralysis), infuse potassium in a suitable concentration at a rate of 40 mmol/hour, up to a rate of 400 mmol/24-hour period.

In critical states, potassium may be infused in saline (unless saline is contraindicated) rather than in glucose solutions, as the latter may decrease serum potassium concentrations.

Diluent's compatibility:

Potassium Chloride 22.3% Concentrated Injection has been reported to be *compatible* with the following IV infusion fluids:

Glucose-Ringers injection combinations, Glucose-lactated Ringers injection combinations, Glucose 5% in lactated Ringers injection, Glucose-saline combinations, Glucose 5% in sodium chloride 0.9%, Glucose 2.5% in water, Glucose 5% in water, Glucose 10% in water, Glucose 20% in water, Ringer's injection, Lactated Ringer's injection, Sodium Chloride 0.45%, Sodium Chloride 0.9% and Sodium Chloride 3%.

4.3 CONTRAINDICATIONS

Renal impairment with oliguria or azotaemia, ventricular fibrillation, untreated Addison's disease, hyperadrenalism associated with adrenogenital syndrome, extensive tissue breakdown as in severe burns, acute dehydration, heat cramps, increased sensitivity to potassium administration as in adynamia episodica hereditaria or congenital paramyotonia and hyperkalaemia of any aetiology.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

The use of potassium salts in patients with chronic renal disease, adrenal insufficiency or any other condition which impairs potassium excretion requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Hypokalaemia should not be treated by the concomitant administration of potassium salts and potassium-sparing diuretics (e.g. spironolactone or triamterene), since the simultaneous administration of these agents can produce severe hyperkalaemia.

In patients on a low-salt diet particularly, hypokalaemic hypochloraemic alkalosis is a possibility that may require chloride as well as potassium supplementation. The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease or acidosis, requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the ECG and the patient's clinical status.

Potassium should be used with caution in diseases associated with heart block since increased serum potassium may increase the degree of block.

Parenteral potassium chloride solutions may cause pain if given in a small vein.

Warnings

In patients with impaired mechanisms for excreting potassium, administration of potassium salts can produce hyperkalaemia and cardiac arrest. This is an important concern in patients given IV potassium. Potentially fatal hyperkalaemia can develop rapidly and be asymptomatic. In patients being given potassium, especially by IV, monitoring of serum electrolytes, the ECG and the patient's clinical status is indicated.

Use in renal impairment

The use of potassium salts in patients with chronic renal disease requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Use in the elderly

No data available.

Paediatric use

No data available.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Potassium Chloride 22.3% Concentrated Injection has been reported to be *incompatible* when diluted in solutions containing the following drugs:

(Note: This list may not be complete)

- Adrenaline HCl
- Atropine Sulfate
- Cephalothin sodium
- Chloramphenicol sodium succinate
- Chlorpromazine HCl
- Diazepam
- Methicillin sodium
- Phenytoin sodium
- Suxamethonium chloride
- Sulfadiazine sodium
- Thiopentone sodium

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy

No data available.

Use in lactation

No data available.

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)

The symptoms and signs of potassium intoxication include paraesthesias of the extremities, flaccid paralysis, listlessness, mental confusion, weakness and heaviness of the legs, fall in blood pressure, cardiac arrhythmias and heart block. Hyperkalemia may exhibit the following ECG abnormalities: disappearance of the P-wave, widening and slurring of QRS complex, changes of the S-T segment, tall-peaked T-waves. Nausea, vomiting, diarrhoea and abdominal discomfort have been reported.

Reporting suspected adverse reactions

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

Symptoms

If excretory mechanisms are impaired, or if IV potassium is administered too rapidly, potentially fatal hyperkalaemia can result (see Section 4.3 Contraindications and Section 4.4 Special Warnings and Precautions for Use). However, hyperkalaemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic ECG changes (peaking of T-waves, loss of P-wave, depression of S-T segment and prolongation of the QT interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest. Should any of these manifestations occur, discontinue potassium administration immediately.

Treatment

If hyperkalaemia develops, the following measures should be considered: elimination of foods and medications containing potassium and of potassium-sparing diuretics; IV administration of 300 to 500 mL/hour of 10% glucose solution containing 10 to 20 units of insulin/1000 mL; correction of acidosis, if present, with IV sodium bicarbonate, use of exchange resins, haemodialysis, or peritoneal dialysis, in presence of life-threatening cardiac arrhythmias, IV administration of 10 to 50 mL calcium gluconate 10% over 5 minutes. Continuous ECG monitoring is mandatory. In treating hyperkalaemia in digitalised patients, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

For information on the management of overdose, contact the Poisons Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Potassium ion is the principal intracellular ion of most body tissues. Potassium ions are involved in a number of essential physiological processes, including the maintenance of intracellular tonicity, the transmission of nerve impulses, the contraction of cardiac, skeletal, and smooth muscle and the maintenance of normal renal function.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Distribution

Potassium ion is the principal intracellular ion of most body tissues.

Excretion

Excretion of potassium occurs via the kidneys and normally any amounts given in excess of intracellular requirements are rapidly eliminated.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Potassium Chloride 22.3% Concentrated Injection contains 2.23 g potassium chloride in water for injections. Contains no preservatives.

6.2 INCOMPATIBILITIES

See Section 4.5 Interactions with Other Medicines and Other Forms of Interactions.

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)[1]. The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Potassium Chloride 22.3% Concentrated Injection is presented in a 10 mL glass vial in a carton of 10 vials.

The vial stopper is not made with natural rubber latex.

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

Chemical structure

The chemical name for potassium chloride is: KCl.
The molecular weight of the compound is 74.55.

CAS number

7447-40-7

[1] AUST R 23073

7 MEDICINE SCHEDULE (POISONS STANDARD)

Unscheduled

8 SPONSOR

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9 DATE OF FIRST APPROVAL

14 October 1991

10 DATE OF REVISION

09 August 2022

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	Minor editorial changes
All	Product name has been revised from ''Potassium Chloride Concentrated Injection'' to ''Potassium Chloride 22.3% Concentrated Injection'' in alignment with updated ARTG good name.
3	Revised - "Potassium Chloride 22.3% Concentrated Injection is a clear colourless sterile solution."
6.5	Deletion of Phebra product code.

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