AUSTRALIAN PRODUCT INFORMATION –[STERILE POTASSIUM CHLORIDE CONCENTRATE (POTASSIUM CHLORIDE)]

1. NAME OF THE MEDICINE

potassium chloride.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sterile Potassium Chloride Concentrate contains:

- 13.4 mmol (1 g) of potassium chloride in 4 mL Steriluer
- 26.8 mmol (2 g) of potassium chloride in 8 mL Steriluer
- 10 mmol (750 mg) of potassium chloride in 10 mL Steriluer
- 13.4 mmol (1 g) of potassium chloride in 10 mL Steriluer
- 20 mmol (1.5 g) of potassium chloride in 10 mL Steriluer

It is a sterile, preservative-free solution of Potassium Chloride.

3. PHARMACEUTICAL FORM

Concentrate for injection.

It is a clear, colourless solution, and free from visible impurities.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- For the prevention and treatment of potassium deficiency (hypokalaemia)
- As an electrolyte supply
- Treatment of digitalis intoxication.

These solutions are for use in patients who are unable to take potassium orally.

These solutions are for the preparation of dilute potassium chloride injections or for addition to intravenous fluids.

4.2 Dose and method of administration

Dosage

Solutions should be diluted before use with not less than the recommended volume of suitable diluent (as indicated on individual labels). Careful and thorough mixing of solution after dilution is essential. Intravenous potassium injections must be given slowly. The rate of administration should not exceed 20 mmol of potassium per hour. The dose is dependent on individual patient requirements but total daily dosage should generally not exceed 150 mmol potassium.

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

If urgent treatment is required, e.g., if serum potassium concentration is 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 glucose may decrease serum potassium concentrations.

***Dilution*:** Potassium chloride concentrate is compatible with most commonly used intravenous infusion fluids.

The product and its admixtures contain no antimicrobial agent. In order to reduce microbiological hazards it is recommended that further dilution be effected immediately prior to use and infusion commenced as soon as practicable after preparation of the admixture. Infusion should be completed within 24 hours of preparation and the residue discarded.

4.3 Contraindications

- hyperkalaemia
- hyperadrenalism associated with adrenogenital syndrome
- tissue breakdown as with severe burns
- acute dehydration
- heat cramps
- renal impairment with oliguria and azotemia
- untreated Addison’s disease
- ventricular fibrillation
- atrioventricular or intraventricular heart block

- any condition which will increase sensitivity to potassium administration such as adynamia episodica hereditaria or congenital paramyotonia and hyperkalaemia of any aetiology.

4.4 Special warnings and precautions for use

- Solutions of potassium chloride MUST BE DILUTED before use according to dilution instructions on individual labels.

- Careful and thorough mixing of solution after dilution is essential.

- In patients with impaired renal function, adrenal insufficiency or impaired mechanisms for excreting potassium, intravenous administration may result in hyperkalaemia or cardiac arrest. This is of particular concern in patients given IV potassium. Potentially fatal hyperkalaemia can develop quickly and without apparent warning. Careful monitoring of serum potassium levels during administration and appropriate adjustment of dosage is essential. It is also recommended that acid-base balance, serum electrolytes, ECG and clinical status of the patient be monitored during therapy.

- Concomitant administration of potassium salts and a potassium-sparing diuretic (e.g. spironolactone or triamterene can produce severe hyperkalaemia.

- Potassium should be used with caution in diseases associated with heart block. High levels of serum potassium may increase the degree of heart block in patients associated with bradycardia.

- 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 patient's ECG and clinical status.

- In patients on a low-salt diet particularly, hypokalaemic hypochloraemic alkalosis is a possibility that may require chloride as well as potassium supplementation.

- Parenteral potassium chloride may cause pain if injected into a small vein.

- Sickle cell disease

Use in the elderly

No data available.

Paediatric use

No data available.

Effects on laboratory tests

No information is available.

4.5 Interactions with other medicines and other forms of interactions

- Potassium sparing diuretics, including triamterene, spironolactone and amiloride, increase potassium retention by reducing renal elimination of the potassium ion and hence can produce severe hyperkalemia.

- ACE Inhibitors including enalapril and captopril elevate serum potassium and may produce hyperkalaemia when administered concurrently with potassium. Ace inhibitors decrease aldosterone secretion, possibly resulting in potassium retention.

- Beta adrenergic agents – beta adrenergic blockade increases both peak serum potassium concentration and the time required for serum potassium to return to basal levels in subjects receiving an acute intravenous potassium load.

- Non steroidal anti-inflammatory drugs (NSAIDs) – may cause hyperkalemia by inducing secondary hypoaldosteronism following inhibition of renal prostaglandin synthesis.

- Heparin – reduces the synthesis of aldosterone which may result in hyperkalemia, especially in patients with underlying renal insufficiency or other problems that impair potassium excretion.

- Diuretics, thiazide – there is an increased risk of hyperkalaemia when a potassium-wasting diuretic is stopped after continued use with a potassium supplement.

- Digitalis glycosides, in the presence of heart block – potassium supplements are not recommended for concurrent use in digitalized patients with severe or complete heart block. Careful monitoring is extremely important if potassium chloride is used to correct hypokalaemia in such patients.

- Insulin – concurrent use may decrease serum potassium.

- Sodium bicarbonate – concurrent use may decrease serum potassium.

For information regarding incompatibilities with other products see Section 6.2 Incompatibilities.

4.6 Fertility, pregnancy and lactation

Effects on fertility

No data available.

Use in pregnancy

Animal reproduction studies have not been performed with potassium chloride. Both potassium and chloride ions are essential constituents of human tissues and fluids. However, supraphysiological levels of potassium are detrimental to maternal and foetal cardiac function. It is also not known whether therapeutic doses of potassium chloride can cause foetal harm when administered to pregnant women. Potassium chloride should be used during pregnancy only when clearly needed. If treatment is required, oral therapy is preferred. Serum levels should be closely monitored in pregnant women receiving potassium therapy.

Use in lactation

Potassium is excreted into breast milk. Because of the potential for potassium to cause serious adverse effects on the breastfeeding baby, caution should be exercised when potassium therapy is given to a breastfeeding woman. However, problems in humans have not been reported.

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:

Cardiovascular

- Fall in blood pressure, cardiac depression arrhythmias and heart block.
- Hyperkalaemia is usually asymptomatic but may exhibit the following ECG abnormalities: disappearance of the P wave, widening and slurring of QRS complex, changes of the ST segment, tall peaked T waves.

Gastrointestinal

Nausea, vomiting, diarrhoea and abdominal discomfort may occur.

Other

Listlessness, mental confusion, paraesthesia of the extremities, weakness and heaviness of the legs, flaccid paralysis.

General

Pain or phlebitis may occur if solutions containing more than 30 mmol/L of potassium are given intravenously.

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

Symptoms

If excretory mechanisms are impaired or if intravenous potassium is administered too rapidly, potentially fatal hyperkalaemia may result from overdosage with potassium chloride (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 ST 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.

Potassium levels of 8 – 11 mmol/L may result in death from cardiac depression, arrhythmias or arrest.

Treatment

If hyperkalaemia develops, the following measures should be considered: elimination of foods and discontinue administration of medicines containing potassium and potassium-sparing diuretics. Parenteral frusemide with substantial doses of sodium chloride and bland fluids will assist excretion of excess potassium through the kidneys.

In renal failure, a cation exchange resin may be given e.g. sodium polystyrene sulphonate 15 g four times daily by mouth or 30 g in 200 mL water as an enema. In severe hyperkalaemia, treatment with haemodialysis or peritoneal dialysis may become necessary.

To correct acidosis, intravenous infusion of sodium bicarbonate 45-150 mEq over 5 minutes, (repeated after 15 to 20 minutes if necessary) has been recommended. In the presence of life-threatening cardiac arrhythmias, discontinue potassium administration immediately. 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 13 11 26 (Australia).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Potassium is an essential body electrolyte found in intracellular fluid where it is the principal cation. It is involved in cell function and metabolism, including maintenance of intracellular acid-base balance and isotonicity, transmission of nerve impulses, contraction of muscle, and maintenance of renal function.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

Distribution

After intravenous administration, potassium is actively transported from extracellular fluid into cells where concentrations reach up to 40 times that of extracellular fluid.

Excretion

It is excreted mainly by the kidneys and is secreted in the distal tubule where it is involved in the sodium-potassium exchange process. Some potassium is excreted in the faeces and small amounts may also be excreted in the sweat, saliva, bile and pancreatic juice.

5.3 Preclinical safety data

Genotoxicity

No data available.

Carcinogenicity

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

6.2 Incompatibilities

Potassium chloride solution has been reported as being incompatible when diluted in solutions containing the following drugs:

- adrenaline hydrochloride
- amikacin sulphate
- amphotericin B
- amoxycillin sodium
- atropine sulphate
- benzylpenicillin
- cephalothin sodium
- chloramphenicol sodium succinate
- chlorpromazine hydrochloride
- diazepam
- dobutamine hydrochloride
- ergotamine tartrate

- etoposide with cisplatin and mannitol
- methicillin sodium
- methylprednisolone sodium succinate
- phenytoin sodium
- promethazine hydrochloride
- sodium nitroprusside
- streptomycin sulfate
- suxamethonium chloride
- sulfadiazine sodium
- thiopentone sodium.

The drugs listed above may not be complete, check compatibility between the additives and potassium chloride solution before mixing.

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

- Glucose-Ringer's injection combinations
- Glucose-lactated Ringer's injection combinations
- Glucose 5% in lactated Ringer's 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%

- Sodium chloride 3%.

Potassium Chloride Injection has been reported to be incompatible with the following IV infusion fluids:

- Mannitol
- Sterile fat emulsions containing soya oil and lecithin

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

Use once only and discard any remaining portion.

6.5 Nature and contents of container

Sterile Potassium Chloride Concentrate is available as:

- 50 x 10 mmol (750 mg) in 10 mL Steriluer plastic ampoule
- 50 x 13.4 mmol (1 g) in 10 mL Steriluer plastic ampoule
- 50 x 20 mmol (1.5 g) in 10 mL Steriluer plastic ampoule
- 50 x 13.4 mmol (1 g) in 4 mL Steriluer plastic ampoule
- 50 x 26.8 mmol (2 g) in 8 mL Steriluer plastic ampoule

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 molecular formula is KCl

CAS number

7447-40-7

7. MEDICINE SCHEDULE (POISONS STANDARD)

Not scheduled

8. SPONSOR

Pfizer Australia Pty Ltd
Level 17, 151 Clarence Street
Sydney NSW 2000
Toll Free Number: 1800 675 229
www.pfizer.com.au

9. DATE OF FIRST APPROVAL

1 g/ 4mL, 750 mg / 10 mL, 1 g/ 10 mL and 1.5 g/ 10 mL plastic ampoule

9 July 1991

2 g/ 8mL plastic ampoule

22 June 1994

10. DATE OF REVISION

07 April 2020

Summary Table of Changes

Section changed	Summary of new information
All	Reformatted in line with the new form
1, 2, 3, 4, 6, 7, 9	Minor Editorial changes
8	Sponsor details update