

New Zealand Data Sheet

1. PRODUCT NAME

Chlorvescent Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorvescent effervescent tablet contains potassium chloride, potassium bicarbonate and citric acid, providing 14mmol potassium (548 mg) and 8 mmol chloride (298 mg) in the form of an acceptable drink.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

White or white to yellow, round and flat tablets

4. CLINICAL PARTICULARS

4.1 Indications

Treatment of potassium deficiency (particularly hypochloremic or hypokalemic alkalosis) associated with diuretic and steroid therapy, vomiting and diarrhoea, ulcerative colitis, steatorrhoea, diabetes insipidus and uncontrolled diabetes mellitus, ileostomy or colostomy patients, cirrhosis and dietary insufficiency.

4.2 Dose and method of administration

1 tablet in half a glass full of water per day is normally sufficient to correct potassium and chloride deficiencies. In more severe depletion, up to 4 tablets (56 mmol potassium and 32 mmol chloride) can be taken daily in divided doses in water.

4.3 Contraindications

Potassium supplements are contraindicated in patients with hyperkalemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest. Hyperkalemia may complicate any of the following conditions: chronic renal impairment, metabolic acidosis such as diabetic acidosis, acute dehydration, extensive tissue breakdown as in severe burns or adrenal insufficiency.

Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (eg. spironolactone or triamterene) since the simultaneous administration of these agents can produce severe hyperkalemia. (see also section 4.5, Interaction with other medicines and other forms of interactions)

4.4 Special warnings and precautions for use

Caution is required in cases of chronic renal disease and hepatic cirrhosis.

In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalaemia and cardiac arrest. This occurs most

commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally.

Potentially fatal hyperkalemia can develop rapidly and may be asymptomatic. The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion.

When interpreting the serum potassium level, the physician should bear in mind that acute alkalosis per se can produce hypokalemia in the absence of a deficit of total body potassium, while acute acidosis per se can increase the serum potassium concentration into the normal range even in the presence of reduced total body potassium. Since the extent of potassium deficiency cannot be accurately determined, it is prudent to proceed cautiously in undertaking potassium replacement, particularly in patients with cardiac disease and those receiving digitalis. Therefore, the treatment of potassium depletion requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the ECG, and the clinical status of the patient.

The safety and effectiveness of this product in children has not been established.

4.5 Interaction with other medicines and other forms of interaction

The simultaneous administration of potassium supplements and a potassium-sparing diuretic can produce severe hyperkalemia (see section 4.3, Contraindications).

Potassium supplements should be used with caution in patients who are using salt substitutes because most of the latter contain substantial amounts of potassium. Such concomitant use could result in hyperkalemia.

Advice to Patients: To minimise the possibility of gastric irritation associated with oral ingestion of concentrated potassium salt preparations, patients should be carefully directed to dissolve each dose completely in the stated amount of water and to take the medication immediately after food.

4.6 Fertility, pregnancy and lactation

Fertility

No data available.

Pregnancy

It is not known whether this product can cause harm to the fetus or affect reproductive capacity when it is administered to a pregnant woman. It should only be given to a pregnant woman if clearly needed.

Lactation

Many drugs are excreted in human milk and because of the potential for serious adverse reaction in nursing infants from oral potassium supplements, a decision

should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines

No data available.

4.8. Undesirable effects

The most common adverse reactions to oral potassium supplements are nausea, vomiting, diarrhoea, and abdominal discomfort. These side effects occur more frequently when the medication is not taken with food or is not diluted properly or dissolved completely. Hyperkalemia occurs only rarely in patients with normal renal function receiving potassium supplements orally. Signs and symptoms of hyperkalemia include the following: cardiac arrhythmias, mental confusion, unexplained anxiety, numbness or tingling in hands, feet or lips, shortness of breath or difficult breathing, unusual tiredness or weakness, and weakness or heaviness of the legs. (see also section 4.4 Special warnings and precautions for use and section 4.9, Overdose).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions

<https://nzphvc.otago.ac.nz/reporting/>

4.9 Overdose

Symptoms and Findings

The administration of oral potassium salts to persons with normal renal function rarely causes serious hyperkalemia. However, in patients with chronic renal disease (or any other condition which impairs potassium excretion), potentially fatal hyperkalemia can result (see section 4.3, Contraindications and section 4.4, Special warnings and precautions for use). The earliest clinical manifestations of this condition may be only increased serum potassium levels and characteristic ECG changes such as peaking of T-waves, loss of P-wave, depression of S-T segment and prolongation of QT interval.

These changes in the ECG usually appear when serum potassium concentration reaches 7 to 8 mmol per litre. Other clinical manifestations, occurring at a concentration of 9 to 10 mmol per litre, may include muscle paralysis and death from cardiac arrest.

Treatment of Overdosage

The treatment of severe hyperkalemia should focus on reducing the serum potassium concentration by promoting the transfer of potassium from the extracellular to the intracellular space. The measures taken may include the following: administration of 10% or 25% glucose solution containing 10 units of insulin per 20g glucose, given intravenously in a dose of 300 to 500 mL per hour; in the acidotic patient, intravenous administration of 150 mmol to 300 mmol of sodium bicarbonate. Other measures should include the elimination of potassium-containing medications and potassium sparing diuretics and frequently the oral administration of a cation exchange resin (such as sodium polystyrene sulfonate) to remove gastrointestinal potassium.

To assure rapid movement of the resin through the gastrointestinal tract, a non-absorbable polyhydric alcohol (eg. sorbitol) should be given in sufficient quantities to induce a soft to semi-liquid bowel movement every few hours. Haemodialysis and peritoneal dialysis are alternative means of removing excess potassium.

Warning: In digitalised patients, too rapid a lowering of potassium levels can cause digitalis toxicity.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Potassium supplement

5.2 Pharmacokinetic properties

Absorption

Potassium chloride is well absorbed from the gastrointestinal tract.

Distribution

It diffuses into extracellular fluid and is then actively transported into cells, achieving an intracellular: extracellular concentration ratio of approximately 40. The normal potassium levels in adults are 3.5-5 mmol/litre.

Excretion

Potassium is excreted primarily by the kidneys, by the processes of filtration, re-absorption and secretion. Excretion of potassium ions is influenced by chloride ion concentration, hydrogen ion exchange, acid-base equilibrium and adrenal mineralocorticoids.

5.3 Preclinical safety data

No data available.

6. Pharmaceutical Precautions

6.1 List of excipients

Acesulfame potassium
Aspartame
Citric acid
Leucine
Macrogol 6000
Ribes nigrum
Sorbitol

6.2 Incompatibilities

No data available.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25°C. Protect from light.

6.5 Nature and contents of container

Tube, plastic, PP with PE stopper. Each tube contains 30 tablets.

6.6 Special precautions for disposal (and other handling)

No data available.

7. MEDICINE SCHEDULE

Pharmacy-Only Medicine

8. SPONSOR

Pharmacy Retailing New Zealand Limited
Trading as Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland
New Zealand

9. DATE OF FIRST APPROVAL

26 May 2005

10. DATE OF REVISION OF THE TEXT

May 2019

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All sections revised	Update to the SPC-style format