CHLORVESCENT

DESCRIPTION:

Each effervescent tablet contains potassium chloride, potassium bicarbonate and potassium carbonate, providing 14 mmol potassium (548 mg) and 8 mmol chloride (283 mg) in the form of an acceptable drink.

Excipients include citric acid- anhydrous, sorbitol, aspartame, acesulfame potassium, leucine, macrogol 6000 and blackcurrant flavour.

PHARMACOLOGY:

Actions

Potassium is the predominant intracellular cation. It plays a vital role in the maintenance of the electrical excitability of nerve and muscle, acid-base balance, and isotonicity. Potassium is an important activator in many enzymatic reactions and is essential to a number of physiological processes including transmission of nerve impulses; contraction of cardiac, smooth, and skeletal muscle; gastric secretion; renal function; tissue synthesis; and carbohydrate metabolism.

Pharmacokinetics

Potassium chloride is well absorbed from the gastrointestinal tract. 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. 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.

INDICATIONS:

For the treatment and specific prevention of hypokalaemia.

CONTRAINDICATIONS:

Potassium supplements should not be used in any of the following conditions:
- hyperkalaemia;
- chronic renal impairment;
- potassium-sparing diuretic therapy (such as triamterene, spironolactone, amiloride);
- acute peptic ulcer or gastritis;
- acute dehydration or heat cramps;
- extensive tissue breakdown (such as burns or crush injuries);
- adrenal insufficiency (such as Addison's disease); or
- if on therapy with any drugs that may cause hyperkalaemia (see Interactions).
PRECAUTIONS:

Potassium salts should be administered with caution to patients with chronic renal disease, liver cirrhosis, cardiac disease. Potassium salts should be given with caution to patients in whom passage through the gastro-intestinal tract may be delayed as in pregnant patients or in those receiving anti-muscarinic agents. Attention should be paid to the concurrent use of other drugs that either contain potassium or have the potential for hyperkalaemia.

Use in Pregnancy

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

Use in Lactation

Many drugs are excreted in human milk and because of the potential for serious adverse reactions 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.

Use in Children

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

INTERACTIONS:

The simultaneous administration of potassium supplements and a potassium-sparing diuretic can produce severe hyperkalaemia (see CONTRAINDICATIONS).

Potassium salts 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 hyperkalaemia.

Concurrent use of a potassium supplement with any of the ACE inhibitors or potassium-sparing diuretics may result in severe hyperkalaemia.

Interactions may also occur in patients simultaneously taking NSAIDs or beta-blockers.

ADVERSE REACTIONS:

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. Hyperkalaemia occurs only rarely in patients with normal renal function receiving potassium supplements orally. Signs and symptoms of hyperkalaemia 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 legs (see also WARNINGS and OVERDOSAGE).
WARNINGS:

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 hyperkalaemia 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 hypokalaemia 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 hypokalaemia 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.

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.

DOSAGE & ADMINISTRATION:

Adults and children 12 years and over: Dissolve 1 or 2 tablets in one-half to one glass of cold water (120 - 240mL) two to three times a day, or as directed by your doctor. Take with or immediately after food. Not for use in children under 12 years of age.

OVERDOSAGE:

The administration of oral potassium salts to persons with normal renal function rarely causes serious hyperkalaemia. However, in patients with chronic renal disease (or any other condition which impairs potassium excretion), potentially fatal hyperkalaemia can result (see CONTRAINDICATIONS and WARNINGS). 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 the 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 hyperkalaemia 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 20 g 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.

Treatment should also involve the administration of calcium to counteract the negative effects of hyperkalaemia on cardiac excitability. If cardiac manifestations of hyperkalaemia are present, then first-line therapy should be with a calcium salt administered intravenously; 10mL to 30mL of calcium gluconate 10% may be given by slow intravenous injection, the dosage being titrated and adjusted based on the ECG improvement. Calcium will not, however, reduce the plasma-potassium concentration.

WARNING: In digitalised patients lowering potassium increases the effect and toxicity of digoxin. Expert advice should be sought.

In the event of overdosage the National Poison Information Centre should be contacted (phone 13 11 26).

PRESENTATION:

Flat, round, white or white to yellow tablet, 60's.

POISON SCHEDULES:

S4

NAME AND ADDRESS OF SPONSOR:

Aspen Pharmacare Australia Pty Ltd
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St Leonards NSW 2065
AUSTRALIA

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