Doctor leaflet

Potassium Oral Solution

Not to be injected.
Must be diluted before drinking.
Dilute the dose in 120 ml (about half a glass) of water or juice and drink slowly.

Composition
Active ingredient : Each 5 ml contains 10 mEq potassium (1.4 g potassium gluconate and 0.43 g potassium citrate).

Action
Potassium is the predominant cation within the cells (approximately 150 to 160 mEq/L) and intracellular sodium content is relatively low. High intracellular potassium concentrations are necessary for numerous cellular metabolic processes.
In extracellular fluid, sodium predominates and the potassium content is low (3.5-5 mEq/L). A membrane-bound enzyme, Na+K+ ATPase, actively transports or pumps sodium out and potassium into cells to maintain these concentration gradients. The intracellular to extracellular potassium gradients are necessary for the conduction of nerve impulses in such specialized tissues as the heart, brain, and skeletal muscle, and for the maintenance of normal renal function and acid-base balance.

Indications
Potassium oral solution is indicated for the prevention and treatment of hypokalemia.

Contraindications
Do not use in patients hypersensitive to any ingredient.
Except under special circumstances, do not use in hyperkalemic patients, or in patients suffering from conditions predisposing to hyperkalemia such as: acute metabolic acidosis, adrenal insufficiency, acute dehydration, uncontrolled diabetes mellitus, chronic renal failure and extensive tissue breakdown, because further increases in serum potassium may cause cardiac arrest.

Warnings
Caution is warranted in patients suffering from severe or prolonged diarrhea resulting in severe dehydration. The loss of fluids in combination with use of potassium supplements may cause renal toxicity, which may increase the risk of hyperkalemia. If potassium supplements are given in the presence of diarrhea, serum potassium levels should be monitored.

A delay in passage of potassium supplements through the gastrointestinal tract caused by stricture or obstruction or peptic ulcer, may cause or worsen gastrointestinal irritation.

Potassium supplements may aggravate familial periodic paralysis or myotonia congenita, although some patients with familial periodic paralysis may require potassium supplementation.

Careful monitoring of serum potassium is warranted in patients with severe or complete heart block, especially in digitalized patients (see Drug Interactions).

Caution is warranted in patients suffering from esophageal compression or delayed gastric emptying.

Use in Pregnancy: Studies have not been done in animals or in humans.
FDA Pregnancy Category C.

Use in Breastfeeding: Problems in humans have not been documented.

Use in the Elderly: Although appropriate studies on the relationship of age to the effects of potassium supplements have not been performed in the geriatric population, no geriatrics-specific problems have been sufficiently documented to date. However, elderly patients are at greater risk of developing hyperkalemia due to age-related changes in the ability of the kidneys to excrete potassium.

Use in Pediatrics: Appropriate studies on the relationship of age to the effects of potassium supplements have not been performed in the pediatric population. However, no pediatrics-specific problems have been sufficiently documented to date.

Adverse Reactions
Hyperkalemia side effects are considered rare when oral dosage forms of potassium are administered to patients having normal renal function. When hyperkalemia is present, symptoms include: severe muscle weakness, unusual tiredness, slow or irregular heartbeat, confusion, numbness or tingling of the hands, feet or lips, unexplained anxiety, shortness of breath or difficult breathing.

Irritation of the alimentary tract may occur when potassium passage is delayed or is in contact with ulcerous areas. Symptoms include: continuing abdominal or stomach pain, cramping, or soreness, chest or throat pain, especially when swallowing, stools containing fresh or digested blood.

The following side effects require medical attention only if they continue or are bothersome: diarrhea, nausea, stomach pain, discomfort, flatulence or mild vomiting. (These side effects occur more frequently when the medication is not taken with food or is not diluted properly.)

Precautions
Patients must be warned not to take salt substitutes or low-salt foods, unless approved by their physician, to prevent excess intake of potassium.
Adequate renal function is essential for therapy with potassium supplements, since the kidneys maintain normal potassium balance. Monitoring of renal function, potassium serum concentrations and ECG is recommended at periodic intervals during oral therapy. The risk/benefit of potassium supplement should be considered in any patient with a higher-than-normal serum creatinine concentration.
Patients must be warned not to begin any strenuous physical exercise, if out of condition, to prevent possible exercise-induced hyperkalemia.

Drug Interactions*:*
Digitalis glycoside, in the presence of heart block: potassium supplements are not recommended for concurrent use in any digitalized patient with severe or complete heart block; however, if potassium supplements must be used to prevent or correct hypokalemia in a digitalized patient, careful monitoring of serum potassium concentrations is extremely important. Abrupt discontinuation of supplemental potassium to a patient suffering

concurrent potassium losses, and also receiving digitalis preparations may result in digitalis toxicity.

Amphotericin B, corticosteroids especially with significant mineralocorticoid activity, corticotropin (ACTH), gentamicin, penicillins or polymyxin B: potassium requirements may be increased in patients receiving these medications due to renal potassium wasting. Close monitoring of serum potassium is recommended.

Angiotensin-converting enzyme inhibitors, beta-adrenergic blocking agents, potassium sparing diuretics, heparin, cyclosporin, non-steroidal anti-inflammatory drugs (NSAIDS): concurrent use with potassium supplements may increase serum potassium concentrations, which may cause severe hyperkalemia and lead to cardiac arrest, especially in renal insufficiency.

Thiazide diuretics: there is an increased risk of hyperkalemia when a potassium-wasting diuretic is discontinued after concurrent use with a potassium supplement.

Low-salt milk, salt substitutes, potassium-containing medications: concurrent use with potassium supplements may increase serum potassium concentrations, which may cause severe hyperkalemia and lead to cardiac arrest, especially in renal insufficiency. Most salt substitutes contain substantial amounts of potassium (low-salt milk may contain potassium up to 60 mEq/L).

Blood from blood bank: blood from blood bank may contain potassium up to 30mEq/L of plasma or up to 65 mEq/L of whole blood when stored for more than 10 days.

Parenteral calcium salts: potassium supplements should be used cautiously in patients receiving parenteral calcium salts because of the danger of precipitating cardiac arrhythmias.

Exchange resins, sodium cycle, such as sodium polystyrene sulfonate: whether these medications are administered orally or rectally, serum potassium concentrations are reduced by sodium replacement of the potassium; fluid retention may occur in some patients because of the increased sodium intake.

Insulin or sodium bicarbonate: concurrent use of these medications with potassium decreases serum potassium concentrations by promoting a shift of potassium ion into the cells.

Laxatives: chronic use or overuse of laxatives may reduce serum potassium concentrations by promoting excessive potassium loss from the intestinal tract.

Anticholinergics or other medications with anticholinergic activity: concurrent use may increase severity of gastrointestinal lesions produced by potassium chloride alone. If symptoms develop, patients should be carefully monitored endoscopically for evidence of lesions.

Dosage and Administration
Each 5 ml Potassium Oral Solution contains 10 mEq potassium.

Caution must be observed in the attempt to correct hypokalemia in order to avoid overcompensation and a resultant hyperkalemia with accompanying cardiac arrhythmias

Adults: the usual adult and adolescent dose is 20 mEq of potassium (10 ml) **diluted in 120 ml (about half a glass) of cold water or juice** two to four times a day. Adjust the dose as needed and tolerated. Do not exceed 100 mEq of potassium a day.

Pediatric: the usual pediatric dose is 20-40 mEq of potassium per square meter of body surface or 2-3 mEq per kg of body weight a day, administered in divided doses and **must be well diluted in water or juice**.

This medication must be taken with or immediately after food, and, after dilution, should be sipped slowly.

The normal adult concentration of serum potassium is 3.5-5 mEq/L with 4.5 mEq often being used for a reference point. Potassium concentrations exceeding 5.5 mEq/L are dangerous because of possible initiation of cardiac arrhythmias. (Normal potassium concentrations tend to be higher in neonates [7.7 mEq/L] than in adults.)

Serum potassium concentrations do not necessarily indicate the true body potassium content. A rise in plasma pH (alkalosis) and chronic acidosis may decrease plasma potassium concentration by promoting potassium excretion and increase the intracellular potassium concentration. Conversely, a decrease in blood pH (acute acidosis) can cause an increase in serum potassium by inhibiting potassium excretion. However, it is necessary to attempt to restore serum potassium to normal in familial periodic paralysis, even though there is no total body potassium depletion. (It may be advisable to monitor serum pH periodically during treatment.)

Overdosage

Treatment of hyperkalemia:

- If appropriate, discontinue blood products, foods and medication that contain potassium, as well as ACE inhibitors, beta blocking agents, nonsteroidal anti-inflammatory drugs, heparin, cyclosporin and potassium-sparing diuretics.
- Administer 10% dextrose containing 10 to 20 units of insulin per liter at a rate of 300 to 500 ml of solution per hour. This will facilitate a shift of potassium into the cells.
- Correct any existing acidosis with 50 mEq intravenous sodium bicarbonate over 5 minutes. The dose may be repeated in 10 to 15 minutes if needed. This will facilitate a shift of potassium into the cells.
- Administer a calcium salt (calcium gluconate, 0.5 to 1 gram, over a 2 minute period) to antagonize the cardiotoxic effects in patients whose ECG show absent P waves, or a broad QRS complex, and who are not receiving digitalis glycosides. Doses may be repeated after 2-minute intervals.
- Use exchange resins to remove excess potassium from the body by adsorption and/or exchange of potassium. The oral dose of sodium polystyrene sulfonate is 20 to 50 grams of the resin dissolved in 100 to 200 ml of 20% sorbitol. The dose may be given every 4 hours up to four or five daily doses until potassium levels return to normal. It may also be given as a retention enema by mixing 8 grams of sodium polystyrene sulfonate and 50 grams of sorbitol in 200 ml of water. The retention enema exchanges potassium faster than the oral sodium polystyrene sulfonate.
- Use hemodialysis or peritoneal dialysis to reduce serum potassium concentrations. This may be necessary in patients with renal function impairment.
- Ascertain adequate urine output and, if not contraindicated by the clinical condition of the patient, maintain a high urine output with normal saline solutions and loop diuretics.

Caution must be observed when treating hyperkalemia in a digitalized patient, since rapid reduction of serum potassium concentrations may induce digitalis toxicity.

List of excipients

Ethanol, citric acid anhydrous, sodium cyclamate, saccharin sodium, tutti frutti flavor, methyl hydroxybenzoate, propyl hydroxybenzoate, purified water.

Pharmaceutical Precautions
Store below 25 ˚C.
After first opening, the medicine could be used for 6 months.

Presentation
Bottle containing 200ml.

Rafa Laboratories Ltd., P. O. Box 405, Jerusalem 9100301

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