POTASSIUM CHLORIDE- potassium chloride solution
Pharmaceutical Associates, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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Potassium Chloride
Oral Solution USP
(20% Solution)
Rx ONLY

DESCRIPTION

Potassium Chloride Oral Solution USP 20% is a sugar-free, clear colorless solution. Each 15 mL (tablespoonful) contains potassium chloride 3.0 g (supplying 40 mEq of potassium and chloride) with alcohol 5%.

The chemical name is potassium chloride, and the structural formula is KCl. Potassium chloride USP occurs as a white, granular powder or as colorless crystals. It is odorless and has a saline taste. Its solutions are neutral to litmus. It is freely soluble in water and insoluble in alcohol.

Inactive Ingredients: Glycerin, purified water, and sodium saccharin.

CLINICAL PHARMACOLOGY

Potassium ion is the principal intracellular cation of most body tissues. Potassium ions participate 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.

The intracellular concentration of potassium is approximately 150 to 160 mEq per liter. The normal adult plasma concentration is 3.5 to 5 mEq per liter. An active ion transport system maintains this gradient across the plasma membrane.

Potassium is a normal dietary constituent and under steady state conditions, the amount of potassium absorbed from the gastrointestinal tract is equal to the amount excreted in the urine. The usual dietary intake of potassium is 50 to 100 mEq per day.

Potassium depletion will occur whenever the rate of potassium loss through renal excretion and/or loss from the gastrointestinal tract exceeds the rate of potassium intake. Such depletion usually develops as a consequence of therapy with diuretics, primary or secondary hyperaldosteronism, diabetic ketoacidosis, or inadequate replacement of potassium in patients on prolonged parenteral nutrition. Depletion can develop rapidly with severe diarrhea, especially if associated with vomiting. Potassium depletion due to these causes is usually accompanied by a concomitant loss of chloride and is manifested by hypokalemia and metabolic alkalosis. Potassium depletion may produce weakness, fatigue, disturbances of cardiac rhythm (primarily ectopic beats), prominent U-waves in the electrocardiogram, and, in advanced cases, flaccid paralysis and/or impaired ability to concentrate urine.

If potassium depletion associated with metabolic alkalosis cannot be managed by correcting the fundamental cause of the deficiency, e.g., where the patient requires long term diuretic therapy, supplemental potassium in the form of high potassium food or potassium chloride may restore normal potassium levels.

In rare circumstances, (e.g., patients with renal tubular acidosis) potassium depletion may be associated with metabolic acidosis and hyperchloremia. In such patients, potassium replacement should be
accomplished with potassium salts other than the chloride, such as potassium bicarbonate, potassium citrate, potassium acetate, or potassium gluconate.

INDICATIONS AND USAGE
1. For the treatment of patients with hypokalemia with or without metabolic alkalosis, in digitalis intoxication, and in patients with hypokalemic familial periodic paralysis. If hypokalemia is the result of diuretic therapy, consideration should be given to the use of a lower dose of diuretic, which may be sufficient without leading to hypokalemia.

2. For the prevention of hypokalemia in patients who would be at particular risk if hypokalemia were to develop, e.g., digitalized patients or patients with significant cardiac arrhythmias.

The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern, and when low doses of the diuretic are used. Serum potassium should be checked periodically, however, and, if hypokalemia occurs, dietary supplementation with potassium-containing foods may be adequate to control milder cases. In more severe cases, and if dose adjustment of the diuretic is ineffective or unwarranted, supplementation with potassium salts may be indicated.

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 failure, systemic acidosis such as diabetic acidosis, acute dehydrations, extensive tissue breakdown as in severe burns, adrenal insufficiency, or the administration of a potassium-sparing diuretic, e.g., spironolactone, triamterene, or amiloride. (See OVERDOSAGE).

Potassium Chloride Oral Solution USP 20% is contraindicated in patients with known hypersensitivity to any ingredient in this product.

WARNINGS
Do not administer full strength. May cause gastrointestinal irritation if administered undiluted. For details regarding adequate dilution, see Dosage and Administration.

Hyperkalemia
(See OVERDOSAGE) In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalemia and cardiac arrest. This occurs most commonly in patients given potassium intravenously, but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and can 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.

Interaction with Potassium-Sparing Diuretics
Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic, e.g., spironolactone, triamterene or amiloride, since the simultaneous administration of these agents can produce severe hyperkalemia.

Interaction with Angiotensin Converting Enzyme Inhibitors
Angiotensin converting enzyme (ACE) inhibitors (e.g., captopril, enalapril) will produce some potassium retention by inhibiting aldosterone production. Potassium supplements should be given to patients receiving ACE inhibitors only with close monitoring.
Metabolic Acidosis

Hypokalemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium bicarbonate, potassium citrate, potassium acetate or potassium gluconate.

PRECAUTIONS

General

The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. In 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 in total body potassium, while acute acidosis per se can increase the serum potassium concentration to within the normal range even in the presence of a reduced total body potassium. 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 electrocardiogram, and the clinical status of the patient.

Information for Patients

Physicians should consider reminding the patient of the following:

To dilute as directed and take each dose after a meal. (See DOSAGE and ADMINISTRATION).

To take this medicine following the frequency and amount prescribed by the physician. This is especially important if the patient is also taking diuretics and/or digitalis preparations.

Laboratory Tests

When blood is drawn for analysis of plasma potassium, it is important to recognize that artifactual elevations can occur after improper venipuncture technique or as a result of in vitro hemolysis of the sample.

Drug Interactions

Potassium-sparing diuretics, angiotensin converting enzyme inhibitors (see WARNINGS).

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, mutagenicity, and fertility studies in animals have not been performed. Potassium is a normal dietary constituent.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with these products. It is unlikely that potassium supplementation that does not lead to hyperkalemia would have an adverse effect on the fetus or would affect reproductive capacity.

Nursing Mothers

The normal potassium ion content of human milk is about 13 mEq per liter. Since oral potassium becomes part of the body potassium pool, as long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.

Pediatric Use
Safety and effectiveness in children have not been established.

**ADVERSE REACTIONS**

One of the most severe adverse effects is hyperkalemia (See CONTRAINDICATIONS, WARNINGS, AND OVERDOSAGE).

The most common adverse reactions to oral potassium salts are nausea, vomiting, flatulence, abdominal pain/discomfort, and diarrhea. These symptoms are due to irritation of the gastrointestinal tract and are best managed by diluting the preparation further, taking the dose with meals, or reducing the amount taken at one time.

Skin rash has been reported rarely.

**OVERDOSAGE**

The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if intravenous administration is too rapid, potentially fatal hyperkalemia can result (See CONTRAINDICATIONS and WARNINGS). It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration (6.5 to 8 mEq/L) and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segments, and prolongation of the QT intervals). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest (9 to 12 mEq/L).

Treatment measures for hyperkalemia include the following:

1. Elimination of foods and medications containing potassium and of any agents with potassium-sparing properties;
2. Intravenous administration of 300 to 500 mL/hr of 10% dextrose solution containing 10 to 20 units of crystalline insulin per 1,000 mL;
3. Correction of acidosis, if present, with intravenous sodium bicarbonate;
4. Use of exchange resins, hemodialysis, or peritoneal dialysis.

In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, lowering the serum potassium concentration too rapidly can produce digitalis toxicity.

**DOSAGE AND ADMINISTRATION**

The usual dietary potassium intake by the average adult is 50 to 100 mEq per day. Potassium depletion sufficient to cause hypokalemia usually requires the loss of 200 or more mEq of potassium from the total body store.

Dosage must be adjusted to the individual needs of each patient. The dose for the prevention of hypokalemia is typically in the range of 20 mEq per day. Doses of 40 to 100 mEq per day or more are used for the treatment of potassium depletion. Deviations from these recommended dosages may be indicated. As no average total daily dose can be defined, the response of the patient to the dose of the drug must be assessed clinically. Larger doses may be required but should be administered under close supervision because of the possibility of potassium intoxication. (See OVERDOSAGE).

**Important:** To assure against gastrointestinal injury and to minimize the possibility of a saline laxative effect, both of which have been associated with the ingestion of concentrated potassium salt preparations, it is recommended that each tablespoonful (15 mL) of this preparation be mixed with at least 6 fluid ounces of water or fruit juice before taking. The dose should also be taken with meals or immediately after eating.
HOW SUPPLIED
Potassium Chloride Oral Solution USP 20% is clear and unflavored and is supplied in the following oral dosage form: NDC 0121-0466-16 in bottles of 16 fl oz (473 mL). Dispense in a tight, light-resistant container as defined in the USP. Protect from freezing.

STORAGE
Keep tightly closed. Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Protect from light.

pai
Pharmaceutical Associates, Inc.
Greenville, SC 29605

R10/14
I046601
R10/14

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label
NDC 0121-0466-16
Potassium Chloride
Oral Solution USP 20%
Dye Free / Sugar Free
40 mEq/15 mL*
*Each 15 mL (1 tablespoonful) contains:
opotassium chloride 3 g supplying 40 mEq of
potassium and chloride. Alcohol 5%.
Rx ONLY
16 fl oz (473 mL)

pai
Pharmaceutical Associates, Inc.
Greenville, SC 29605
POTASSIUM CHLORIDE
potassium chloride solution

Product Information

Product Type: HUMAN PRESCRIPTION DRUG
Item Code (Source): NDC:0121-0466
Route of Administration: ORAL

Active Ingredient/Active Moiety

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Inactive Ingredients

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Packaging

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**Labeler** - Pharmaceutical Associates, Inc. (044940096)

### Establishment

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Revised: 1/2015