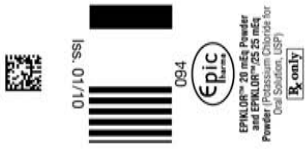


EPIKLOR™ 20 mEq Powder
and EPIKLOR™/25 25 mEq Powder
(Potassium Chloride for Oral Solution, USP)

℞ only

DESCRIPTION

Fruit-flavored EPIKLOR™ and EPIKLOR™/25 Powder (Potassium Chloride for Oral Solution, USP) are oral potassium supplements offered as powder for reconstitution in individual packets. Each packet of EPIKLOR™ powder contains potassium 20 mEq and chloride 20 mEq provided by potassium chloride 1.5 g. Each packet of EPIKLOR™/25 powder contains potassium 25 mEq and chloride 25 mEq provided by potassium chloride 1.875 g. EPIKLOR™ and EPIKLOR™/25 are sugar-free and saccharin-free.

Inactive ingredients: FD&C Yellow #6, sucralose, silicon dioxide, maltodextrin, citric acid and orange flavor.

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.

Potassium depletion may 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 slowly as a consequence of prolonged therapy with oral diuretics, primary or secondary hyperaldosteronism, diabetic ketoacidosis, severe diarrhea, or inadequate replacement of potassium in patients on prolonged parenteral nutrition. Potassium depletion due to these causes is usually accompanied by a concomitant deficiency 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 impair ability to concentrate urine.

Potassium depletion associated with metabolic alkalosis is managed by correcting the fundamental causes of the deficiency whenever possible and administering supplemental potassium chloride, in the form of high potassium food or potassium chloride solution or tablets.

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 or potassium acetate.

INDICATIONS AND USAGE

1) For therapeutic use in patients with hypokalemia with or without metabolic alkalosis; in digitalis intoxication and in patients with hypokalemic familial periodic paralysis.

2) For prevention of potassium depletion when the dietary intake of potassium is inadequate in the following conditions: patients receiving digitalis and diuretics for congestive heart failure; hepatic cirrhosis with ascites; states of aldosterone excess with normal renal function; potassium-losing nephropathy and certain diarrheal states.

3) The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern. 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 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 dehydration, extensive tissue breakdown as in severe burns, adrenal insufficiency, or the administration of a potassium-sparing diuretic (e.g., spironolactone, triamterene or amiloride). Contraindicated in persons demonstrating allergy to any of the components of the powder.

WARNINGS

Hyperkalemia: 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 by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and 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 adjustments.

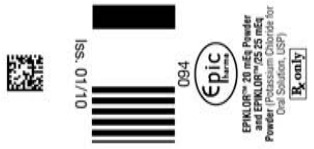
Interaction with Potassium-Sparing Diuretics: Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g., spironolactone, triamterene or amiloride), since the simultaneous administration of these agents can produce severe hyperkalemia.

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

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.

Laboratory Tests: In interpreting the serum potassium level, the physician should be aware 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 into 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.



Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenicity, mutagenicity and fertility studies in animals have not been performed. Potassium is a normal dietary constituent.

Pregnancy: Pregnancy Category C. Animal reproduction studies have not been conducted with potassium chloride. It is not known if potassium chloride causes fetal harm when administered to a pregnant woman or affects reproductive capacity. Potassium chloride should be given to a pregnant woman only if clearly needed.

Nursing Mothers: 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.

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

ADVERSE REACTIONS

The most common adverse reactions to oral potassium salts are nausea, vomiting, abdominal 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 dose.

One of the most severe adverse effects is hyperkalemia (see **CONTRAINDICATIONS**, **WARNINGS** and **OVERDOSAGE**). 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 potassium is administered too rapidly intravenously, 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 and characteristic electrocardiographic changes (peaking of T-waves, loss of P-wave, depression of S-T segment and prolongation of the QT interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest.

Treatment measures for hyperkalemia include the following: (1) elimination of foods and medications containing potassium and of potassium-sparing diuretics; (2) intravenous administration of 300 to 500 mL/hr of 10% dextrose solution containing 10-20 units of 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, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

DOSAGE AND ADMINISTRATION

Dosage must be adjusted to the individual needs of each patient but is typically in the range of 20 mEq per day for the prevention of hypokalemia to 40-100 mEq per day or more for the treatment of potassium depletion.

The usual adult dose is 20-100 mEq of potassium per day (one EPIKLOR™ 20 mEq packet 1 to 5 times daily after meals or one EPIKLOR™/25 25 mEq packet 1 to 4 times daily after meals).

The contents of each EPIKLOR™ packet should be dissolved in at least 4 ounces of cold water or other beverage. The contents of each EPIKLOR™/25 packet should be dissolved in at least 5 ounces of cold water or other beverage. These preparations, like other potassium supplements, must be properly diluted to avoid the possibility of gastrointestinal irritation.

HOW SUPPLIED

EPIKLOR™ Powder (Potassium Chloride for Oral Solution, USP) 20 mEq is supplied in cartons of 30 and 100 packets. Each packet contains potassium 20 mEq and chloride 20 mEq provided by potassium chloride 1.5 g.

EPIKLOR™/25 Powder (Potassium Chloride for Oral Solution, USP) 25 mEq is supplied in cartons of 30 and 100 packets. Each packet contains potassium 25 mEq and chloride 25 mEq provided by potassium chloride 1.875 g.

Store at Controlled Room Temperature, 20-25°C (68-77°F). [See USP Controlled Room Temperature].

Manufactured by:
Epic Pharma, LLC
Laurelton, NY 11413

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