POTASSIUM CHLORIDE for oral solution

INDICATIONS AND USAGE

POTASSIUM CHLORIDE is indicated for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients in whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient. (1)

Usage

Potassium Chloride for Oral Solution, USP 20 mEq Each pouch contains 1.5 g of Potassium Chloride providing potassium 20 mEq and chloride 20 mEq. (5)

CONTRAINDICATIONS

Contraindicated use with potassium-sparing diuretics. (6)

WARNINGS AND PRECAUTIONS

Gastrointestinal Irritation: Observe before use, take with meals (5.5)

ADVERSE REACTIONS

Most common adverse reactions are nausea, vomiting, flatulence, and diarrhea. (2.5)

To report SUSPECTED ADVERSE REACTIONS, contact Pharm-Olam

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Dosage and Administration

Monitor serum potassium and adjust dosage accordingly (2.2, 5.1) Further, potassium concentration is <7.5 mEq/L, use intravenous potassium instead of oral supplementation (2.2)

Treatment of Hypokalemia

Adult: Initial dose range from 40 to 100 mEq/day in 2 to 5 divided doses; limit doses to 40 mEq per day. Total daily dose should not exceed 200 mEq/day. (2.2)

Pediatric patients aged birth to 16 years old: Typical dose is 1 mEq/kg/day. Do not exceed 2 mEq/kg/day. (2.2, 5.1)

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The normal potassium ion content of human milk is about 13 mg per liter. Hence oral potassium becomes part of the body potassium pool, so 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.

5.2 Pediatric Use

Clinical trials data from published literature have demonstrated the safety and effectiveness of potassium chloride in children with diarrhea and malnutrition from birth to 18 years.

6.4 Geriatric Use

Clinical studies of Potassium Chloride did not include sufficient numbers of elderly patients to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified responses to therapy related to age.

In geriatric patients, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range and adjusting, if necessary, until an appropriate response is achieved.

6.5 Pregnancy

There is no evidence of risk if Potassium Chloride is used as a dietary supplement in pregnancy. Potassium is a normal dietary constituent and the maternal serum potassium level usually remains normal throughout pregnancy. Maternal potassium levels may increase if potassium supplements are given. However, in pregnant women with heart failure or renal insufficiency, serum potassium levels may be increased. Such patients should be monitored more closely.

6.6 Nursing Mothers

Potassium chloride is excreted in breast milk. The normal potassium ion content of human milk is about 13 mg per liter. The adult plasma concentration is 3.5 to 5 mEq per liter. One could expect that the breastfed infant would receive about 9 to 12 mEq/L.

7.8.4 Geriatric Use

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

7.3 Cerebrovascular

Patients with cerebrovascular disease should usually be started at the low end of the dosing range, and the serum potassium level should be monitored frequently. [see Clinical Pharmacology (12.3)]

8.6 Treatment

Treatment measures for hyperkalemia include the following:

5.1 Administer intravenous calcium gluconate if the patient is at risk or has developed digitalis toxicity.

5.2 Administer intravenous sodium bicarbonate, 10 to 20 mEq per 100 mL of 5% dextrose solution.

5.3 Administer a non-electrolyte diuretic, or a agent with potassium-sparing properties such as diuretics, and reduce any agents that may be producing hyperkalemia.

5.4 Administer intravenous sodium bicarbonate to increase the pH, which may decrease the serum potassium concentration.

5.5 Administer replacement fluids, which must be intravenous.

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