POTASSIUM CHLORIDE for oral solution

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use POTASSIUM CHLORIDE safely and effectively. See full prescribing information for POTASSIUM CHLORIDE.

IMPORTANT SAFETY INFORMATION

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

DOSEAGE AND ADMINISTRATION

Doses prior to administration (2.1, 5.1).
Monitor serum potassium and adjust dosage accordingly (2.2, 3.3).
For serum potassium concentration < 2.5 mEq/L, use intravenous potassium instead of oral supplementation (2.1).

Treatment of Hypokalemia:
Adults: Initial dose range from 40 to 100 mEq/day in 2 to 5 divided doses. Total daily dose should not exceed 200 mEq (2.2). Pediatric patients aged 1 to 12 years old: initial dose is 2 mEq/kg/day in divided doses, not to exceed 1 mEq/kg/day as a single dose or 40 mEq, whichever is lower. If deficits are severe or ongoing losses are great, consider intravenous therapy. Total daily dose should not exceed 100 mEq (2.3). Maintenance or Prophylaxis of Hypokalemia:
Adults: Typical dose is 20 mEq per day (2.2). Pediatric patients aged 1 to 12 years old: typical dose is 1 mEq/kg/day. Do not exceed 1 mEq/kg/day (2.3).

DOSE FORMS AND STRENGTHS—

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. (3)

CONTRAINDICATIONS—
Concomitant use with potassium sparing diuretics. (4)

WARNINGS AND PRECAUTIONS—
Gastrointestinal Irritation: Dilute before use, take with meals (5.1).

ADVERSE REACTIONS—
Most common adverse reactions are nausea, vomiting, flatulence, abdominal pain/discomfort, and diarrhea. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Pharo-Olam at 1-800-511-6754 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DIAGNOSTIC OR THERAPEUTIC USE—

Potassium Chloride for Oral Solution, USP 20 mEq.

USE IN SPECIFIC POPULATIONS—

Carcinoma: Initiate therapy at the low end of the dosing range (8.5).
Renal Impairment: Initiate therapy at the low end of the dosing range (8.8).

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Sections or subsections omitted from the full prescribing information are not found.

FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

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

2. DOSAGE AND ADMINISTRATION

2.1 Administration and Monitoring

If serum potassium concentration < 2.5 mEq/L, use intravenous potassium instead of oral supplementation. Monitoring Monitor serum potassium and adjust dosage accordingly. For treatment of hypokalemia, monitor potassium levels daily or more often depending on the severity of hypokalemia until they return to normal. Monitor potassium levels monthly to biannually for maintenance or prophylaxis. The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis requires careful attention to acid-base balance, volume status, electrolytes, including magnesium, sodium, chloride, phosphorus, and calcium, electrocardiograms and the clinical status of the patient. Correct volume status, acid-base balance and electrolyte deficits as appropriate.

3. CONTRAINDICATIONS

Potassium chloride is contraindicated in patients on potassium sparing diuretics. (3.1)

4. WARNINGS AND PRECAUTIONS

5. ADVERSE REACTIONS

6. DRUG INTERACTIONS

7. POTASSIUM Sparing Diuretics

Use with potassium-sparing diuretics can produce severe hyperkalemia. Avoid concomitant use. (7.1)

2. Angiotensin-Converting Enzyme Inhibitors

Use with angiotensin-converting enzyme (ACE) inhibitors produces potassium retention by inhibiting aldosterone production. Potassium supplementation should be given to patients receiving ACE inhibitors only with close monitoring. (7.2)

3. Angiotensin Receptor Blockers

Use with angiotensin receptor blockers (ARBs) produces potassium retention by inhibiting aldosterone production. Potassium supplements should be given to patients receiv ing ARBs only with close monitoring. (7.3)

8. USE IN SPECIFIC POPULATIONS

9. Pregnancy

Pregnancy Category C

10. OVERDOSAGE

11. DESCRIPTIONS

12. CLINICAL PHARMACOLOGY

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16. HOW SUPPLIED/STORAGE AND HANDLING

Sections or subsections omitted from the full prescribing information are not found.
The bioavailability of potassium from KCl oral solution were higher during the first few hours after dosing relative to modified release KCl products. The bioavailability of potassium, as measured by the cumulative urinary excretion of K+ over a 24-hour post dose period, is similar for KCL solution and modified release products.

4.5 Renal Impairment

Patients with renal impairment have reduced urinary excretion of potassium and are at substantially increased risk of hyperkalemia. Patients with impaired renal function, particularly if the patient is on ACE inhibitors, ARBs, or nonsteroidal anti-inflammatory drugs, should usually be started at the low end of the dosing range because of the potential for development of hyperkalemia. The serum potassium level should be monitored frequently. Renal function should be assessed periodically.

10.2 Treatment

Treatment measures for hyperkalemia include the following:
1. Minimize closely for arrhythmias and electrolyte changes.
2. Eliminate foods and medications containing potassium and of any agents with potassium-sparing properties such as potassium-sparing diuretics, ARBS, ACE inhibitors, NSAIDS, certain anti-inflammatory drugs, and nonsteroidal anti-inflammatory drugs.
3. Administer intravenous calcium gluconate if the patient is at no risk or low risk of developing digitalis toxicity.
4. Administer intravenously 500 to 500 mL/hr of 10% dextrose solution containing 10 to 20 units of insulin per 1000 mL.
5. Correct acidosis, if present, with intravenous sodium bicarbonate.
6. Use exchange resins, hemodialysis, or peritoneal dialysis.
7. In patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can cause acute profound digitalis toxicity. The serum potassium level should be monitored frequently. Renal function should be assessed periodically.

11 DESCRIPTION

Potassium Chloride is a white crystalline or colorless solid. It is soluble in water and slightly soluble in alcohol. Chemically, Potassium Chloride is KCL, a white solid with a molecular mass of 74.55.

Each pouch of light pink to orange powder contains 1.5 g of potassium chloride, USP, which is equivalent to potassium 20 mEq and chloride 20 mEq.

22 CLINICAL PHARMACOLOGY

22.1 Mechanism of Action

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

5.4 Geriatric Use

Clinical studies of Potassium Chloride did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, and should be modified according to the patient's response.

8.2 Nursing Mothers

Since 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.

8.3 Pediatric Use

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

8.4 Gonadal Use

Clinical studies of Potassium Chloride did not include sufficient numbers of subjects of reproductive capacity, and it is unknown whether Potassium Chloride might cause fetal harm when administered to a pregnant woman. Potassium Chloride should not be used in women of reproductive capacity, and when used, the patient should be warned of the possible hazard to the fetus.

9.3 Pregnancy

Pregnancy Category C

An animal reproduction study has not been done with oral potassium salts. Potassium Chloride should not be given to pregnant women unless clearly needed.

14 HOW SUPPLIED/STORAGE AND HANDLING

Potassium Chloride Oral Solution, is a light pink to orange powder supplied in one strength as follows:

20 mEq

NDC: 6805-1554-10 pouches. Each pouch contains 5.9 g of potassium chloride providing potassium 20 mEq and chloride 20 mEq.

NDC: 6805-1554-15 carton of 30 pouches.

Store at Controlled Room Temperature, 25°C (77°F); excursions are permitted to 15°C to 30°C (59°F to 86°F). Dispense in a tight, light-resistant container as defined in the USP. PROTECT from LIGHT.