

POTASSIUM CHLORIDE - potassium chloride solution
Safecor Health, LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

POTASSIUM CHLORIDE oral solution

Initial U.S. Approval: 1948

----- **INDICATIONS AND USAGE** -----

Potassium chloride oral solution 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 are insufficient. (1)

----- **DOSAGE AND ADMINISTRATION** -----

Dilute prior to administration. (2.1, 5.1)

Monitor serum potassium and adjust dosage accordingly. (2.2, 2.3)

Treatment of hypokalemia:

- Adults: Initial doses range from 40 to 100 mEq/day in 2 to 5 divided doses: limit doses to 40 mEq per dose. Total daily dose should not exceed 200 mEq. (2.2)
- Pediatric patients aged birth to 16 years old: 2 to 4 mEq/kg/day in divided doses; not to exceed 1 mEq/kg as a single dose or 20 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 birth to 16 years old: typical dose is 1 mEq/kg/day. Do not to exceed 3 mEq/kg/day. (2.3)

----- **DOSAGE FORMS AND STRENGTHS** -----

- Oral Solution: 10%; 1.3 mEq potassium per mL (3)
- Oral Solution: 20%; 2.6 mEq potassium per mL (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 Apotex Corp. at 1-800-706-5575 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----- **DRUG INTERACTIONS** -----

- Potassium sparing diuretics: Avoid concomitant use. (7.1)
- Angiotensin converting enzyme inhibitors: Monitor for hyperkalemia. (7.2) Angiotensin receptor blockers: Monitor for hyperkalemia. (7.3)

Revised: 5/2019

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Potassium chloride oral solution is indicated for the treatment and prophylaxis of hypokalemia in patients for whom dietary management with potassium-rich foods or diuretic dose reduction are insufficient.

2 DOSAGE AND ADMINISTRATION

2.1 Administration and Monitoring

Monitoring

Monitor serum potassium and adjust dosages 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, phosphate, and calcium, electrocardiograms and the clinical status of the patient. Correct volume status, acid-base balance and electrolyte deficits as appropriate.

Administration

Dilute the potassium chloride solution with at least 4 ounces of cold water [see *Warnings and Precautions (5.1)*].

Take with meals or immediately after eating.

If serum potassium concentration is less than 2.5 mEq/L, use intravenous potassium instead of oral supplementation.

2.2 Adult Dosing

Treatment of hypokalemia

Daily dose range from 40 to 100 mEq. Give in 2 to 5 divided doses: limit doses to 40 mEq per dose. The total daily dose should not exceed 200 mEq in a 24 hour period.

Maintenance or Prophylaxis

Typical dose is 20 mEq per day. Individualize dose based upon serum potassium levels.

Studies support the use of potassium replacement in digitalis toxicity. When alkalosis is present, normokalemia and hyperkalemia may obscure a total potassium deficit. The advisability of use of potassium replacement in the setting of hyperkalemia is uncertain.

2.3 Pediatric Dosing

Treatment of hypokalemia

Pediatric patients aged birth to 16 years old: The initial dose is 2 to 4 mEq/kg/day in divided doses; do not exceed as a single dose 1 mEq/kg or 40 mEq, whichever is lower; maximum daily doses should not exceed 100 mEq. If deficits are severe or ongoing losses are great, consider intravenous therapy.

Maintenance or Prophylaxis

Pediatric patients aged birth to 16 years old: Typical dose is 1 mEq/kg/day. Do not exceed 3 mEq/kg/day.

3 DOSAGE FORMS AND STRENGTHS

Oral Solution 10%: 1.3 mEq potassium per mL. Oral Solution 20%: 2.6 mEq potassium per mL.

4 CONTRAINDICATIONS

Potassium chloride is contraindicated in patients on potassium sparing diuretics.

5 WARNINGS AND PRECAUTIONS

5.1 Gastrointestinal Irritation

May cause gastrointestinal irritation if administered undiluted. Increased dilution of the solution and taking with meals may reduce gastrointestinal irritation [*see Dosage and Administration (2.1)*].

6 ADVERSE REACTIONS

The most common adverse reactions to oral potassium salts are nausea, vomiting, flatulence, abdominal pain/discomfort, and diarrhea.

7 DRUG INTERACTIONS

7.1 Potassium-Sparing Diuretics

Use with potassium-sparing diuretic can produce severe hyperkalemia. Avoid concomitant use.

7.2 Angiotensin-Converting Enzyme Inhibitors

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

7.3 Angiotensin Receptor Blockers

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with potassium chloride. 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.

8.2 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, 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

The safety and effectiveness of potassium chloride have been demonstrated in children with diarrhea and malnutrition from birth to 18 years.

8.4 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 the 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, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

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 more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

10 OVERDOSAGE

10.1 Symptoms

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 potentially fatal hyperkalemia can result.

Hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration (6.5 to 8.0 mEq/L) and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the QT-interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest (9 to 12 mEq/L).

10.2 Treatment

Treatment measures for hyperkalemia include the following:

1. Monitor 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 nutritional supplements and many others.
3. Administer intravenous calcium gluconate if the patient is at no risk or low risk of developing digitalis toxicity.
4. Administer intravenously 300 to 500 mL/hr of 10% dextrose solution containing 10 to 20 units of crystalline insulin per 1000 mL.
5. Correct acidosis, if present, with intravenous sodium bicarbonate.
6. Use exchange resins, hemodialysis, or peritoneal dialysis.

In patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

11 DESCRIPTION

Potassium chloride, USP is a colorless, elongated, prismatic, or cubical crystals, or white, granular powder. It is soluble in water and slightly soluble in alcohol. Chemically, potassium chloride is K-Cl with a molecular mass of 74.55 g/mol.

Oral Solution 10%: Each 15 mL of solution contains 1.5 g of potassium chloride, USP and the following inactive ingredients: citric acid anhydrous, FD&C Yellow #6, glycerin, methylparaben, natural orange flavor, propylene glycol, propylparaben, purified water, sodium citrate dihydrate, sucralose.

Oral Solution 20%: Each 15 mL of solution contains 3.0 g of potassium chloride, USP and the following inactive ingredients: citric acid anhydrous, FD&C Yellow #6, glycerin, methylparaben, natural orange flavor, propylene glycol, propylparaben, purified water, sodium citrate dihydrate, sucralose.

Natural orange flavor includes fruit extract and natural flavor.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The potassium ion (K^+) 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.

12.3 Pharmacokinetics

Based on published literature, the rate of absorption and urinary excretion 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.

16 HOW SUPPLIED/STORAGE AND HANDLING

Potassium chloride oral solution, USP is an orange solution available in two strengths as follows:

10%: 20 mEq/15 mL oral solution

NDC# 48433-217-15 Unit Dose Cup of 15 mL

NDC# 48433-217-40 Box of 40 Unit Dose Cups, each with 15 mL

20%: 40 mEq/15 mL oral solution

NDC# 48433-218-15 Unit Dose Cup of 15 mL

NDC# 48433-218-40 Box of 40 Unit Dose Cups, each with 15 mL

For Institutional Use Only

This Package is Not Child Resistant

Storage

Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].

PROTECT from LIGHT.

POTASSIUM CHLORIDE ORAL SOLUTION, USP, 10% and 20%

Packaged by:

Safecor Health, LLC
4060 Business Park Drive
Columbus, OH 43204

Manufactured by:

Apotex Inc.
Toronto, Ontario
Canada M9L 1T9

Manufactured for:

Apotex Corp.
Weston, Florida
USA 33326

Rev: 03/2019 PN5644

Principal Display Panel - 10% Box Label

**SAFECOR
HEALTH**

NDC: 48433-217-40

Potassium Chloride Oral Solution USP 10%

Contains 40 (15mL) Unit Dose Cups

See package insert for complete drug information

Store at 20° to 25°C (68° to 77°F) See USP Controlled Room Temperature

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN

Rx ONLY

FOR INSTITUTIONAL USE ONLY

Pkg By: Safecor Health, LLC Columbus, OH 43204.

Questions or Comments: Cal 1-800-447-1006

GTN: 00348433217405

SN: 192000028

Exp: 201212

Lot: SC050819

5682.A

SAFECOR
HEALTH

Potassium Chloride

Oral Solution USP 10%

Contains 40 (15mL) Unit Dose Cups

See package insert for complete drug information.

Store at 20° to 25°C (68° to 77°F) See USP Controlled Room Temperature

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN



Rx ONLY

FOR INSTITUTIONAL USE ONLY

Pkg By: Safecor Health, LLC Columbus, OH 43204.

Questions or Comments: Call 1-800-447-1006

NDC: 48433-217-40



GTIN: 00348433217405

SN: 192000028

Exp: 201212

Lot: SC050819

SAFECOR
HEALTH

Potassium Chloride

Oral Solution USP 10%

Contains 40 (15mL) Unit Dose Cups

See package insert for complete drug information.

Store at 20° to 25°C (68° to 77°F) See USP Controlled Room Temperature

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN



Rx ONLY

FOR INSTITUTIONAL USE ONLY

Pkg By: Safecor Health, LLC Columbus, OH 43204.

Questions or Comments: Call 1-800-447-1006

NDC: 48433-217-40



GTIN: 00348433217405

SN: 192000028

Exp: 201212

Lot: SC050819

5682.A

Principal Display Panel - 10% Lid Label

Delivers 15mL

NDC 48433-217-15

Potassium Chloride Oral Solution USP 10%

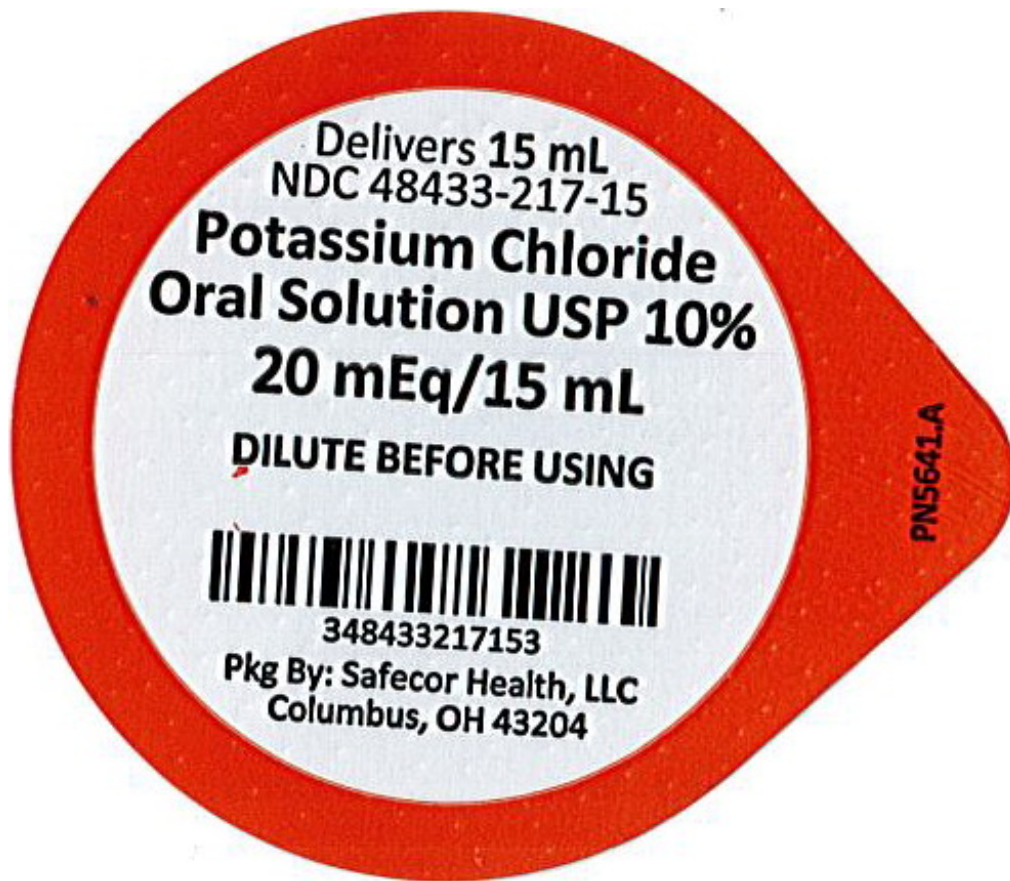
20 mEq/15 mL

DILUTE BEFORE USING

Pkg By: Safecor Health, LLC

Columbus, OH 43204

PN5641.A



Principal Display Panel - 10% Box Label

**SAFECOR
HEALTH**

NDC: 48433-218-40

Potassium Chloride Oral Solution USP 20%

Contains 40 (15mL) Unit Dose Cups

See package insert for complete drug information

Store at 20° to 25°C (68° to 77°F) See USP Controlled Room Temperature
KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN

Rx ONLY

FOR INSTITUTIONAL USE ONLY

Pkg By: Safecor Health, LLC Columbus, OH 43204.

Questions or Comments: Cal 1-800-447-1006

GTN: 00348433218402

SN: 192000031

Exp: 201213

Lot: CS050819

5682.A

SAFECOR
HEALTH

Potassium Chloride

Oral Solution USP 20%

NDC: 48433-218-40

Contains 40 (15mL) Unit Dose Cups

See package insert for complete drug information.

Store at 20° to 25°C (68° to 77°F) See USP Controlled Room Temperature

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN



Rx ONLY
FOR INSTITUTIONAL USE ONLY



GTIN: 00348433218402
SN: 192000031
Exp: 201213
Lot: CS050819

Pkg By: Safecor Health, LLC Columbus, OH 43204.
Questions or Comments: Call 1-800-447-1006

SAFECOR
HEALTH

Potassium Chloride

Oral Solution USP 20%

NDC: 48433-218-40

Contains 40 (15mL) Unit Dose Cups

See package insert for complete drug information.

Store at 20° to 25°C (68° to 77°F) See USP Controlled Room Temperature

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN



Rx ONLY
FOR INSTITUTIONAL USE ONLY



GTIN: 00348433218402
SN: 192000031
Exp: 201213
Lot: CS050819

Pkg By: Safecor Health, LLC Columbus, OH 43204.
Questions or Comments: Call 1-800-447-1006

5683.A

Principal Display Panel - 20% Lid Label

Delivers 15mL

NDC 48433-218-15

Potassium Chloride Oral Solution USP 20%

40 mEq/15 mL

DILUTE BEFORE USING

Pkg By: Safecor Health, LLC
Columbus, OH 43204

PN5641.A



POTASSIUM CHLORIDE

potassium chloride solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:48433-217(NDC:60505-6184)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Potassium Chloride (UNII: 660YQ98I10) (Potassium Cation - UNII:295O53K152, Chloride Ion - UNII:Q32ZN48698)	Potassium Chloride	20 meq in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	ORANGE	Score	
Shape		Size	
Flavor	ORANGE (ORANGE)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48433-217-40	40 in 1 BOX, UNIT-DOSE	05/24/2019	
1	NDC:48433-217-15	15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211067	05/24/2019	

POTASSIUM CHLORIDE

potassium chloride solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:48433-218 (NDC:60505-6185)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Potassium Chloride (UNII: 660 YQ98I10) (Potassium Cation - UNII:295O53K152, Chloride Ion - UNII:Q32ZN48698)	Potassium Chloride	40 meq in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	ORANGE	Score	
Shape		Size	
Flavor	ORANGE (ORANGE)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48433-218-40	40 in 1 BOX, UNIT-DOSE	05/24/2019	
1	NDC:48433-218-15	15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211067	05/24/2019	

Labeler - Safecor Health, LLC (828269675)

Establishment

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		828269675	repack(48433-217, 48433-218)

Revised: 5/2019

Safecor Health, LLC