POTASSIUM CHLORIDE - potassium chloride solution **Aurobindo Pharma Limited**

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.

POTASSIUM CHLORIDE oral solution

Initial U.S. Approval: 1948

··· 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 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 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 birth to 16 years old: typical dose is 1 mEq/kg/day. Do not exceed 3 mEq/kg/day (2.3)

..... DOSAGE FORMS AND STRENGTHS

- Oral Solution: 10%; 1.3 mEq potassium per mL (2)
 Oral Solution: 20%; 2.6 mEq potassium per mL (3)

......CONTRAINDICATIONS

• Concomitant use with potassium sparing diuretics. (4)

- Gastrointestinal Irritation: Dilute before use, take with meals (5.1)
- ADVERSE REACTIONS

Most common adverse reactions are nausea, vomiting, flatulence, abdominal pain/discomfort, and

To report SUSPECTED ADVERSE REACTIONS, contact Aurobindo Pharma USA, Inc. at 1-866-850-2876 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

..... DRUG INTERACTIONS

- Potassium sparing diuretics: Avoid concomitant use (7.1)
- Renin-angiotensin-aldosterone inhibitors: Monitor for hyperkalemia (7.2)
 Nonsteroidal Anti-Inflammatory drugs: Monitor for hyperkalemia (7.3)

.....USE IN SPECIFIC POPULATIONS

Cirrhosis: Initiate therapy at the low end of the dosing range (8.5)

Renal Impairment: Initiate therapy at the low end of the dosing range (8.6)

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Revised: 10/2024

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 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 <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 diuretics can produce severe hyperkalemia. Avoid concomitant use.

7.2 Renin-Angiotensin-Aldosterone System Inhibitors

Drugs that inhibit the renin-angiotensin-aldosterone system (RAAS) including angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), spironolactone, eplerenone, or aliskiren produce potassium retention by inhibiting aldosterone production. Closely monitor potassium in patients receiving concomitant RAAS therapy.

7.3 Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

NSAIDS may produce potassium retention by reducing renal synthesis of prostaglandin E and impairing the renin-angiotensin system. Closely monitor potassium in patients on concomitant NSAIDs.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There are no human data related to use of Potassium Chloride during pregnancy, and animal studies have not been conducted. Potassium supplementation that does not lead to hyperkalemia is not expected to cause fetal harm.

The background risk for major birth defects and miscarriage in the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

8.2 Lactation

Risk Summary

The normal potassium ion content of human milk is about 13 mEq per liter. Since potassium from oral supplements such as Potassium Chloride 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.

8.4 Pediatric Use

The safety and effectiveness of potassium chloride have been demonstrated in children with diarrhea and malnutrition from birth to 16 years.

8.5 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.

8.6 Cirrhotics

Patients with cirrhosis 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)].

8.7 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 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.
- 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 white crystalline powder or colourless crystals. It is freely soluble in water, practically insoluble in ethanol. Chemically, Potassium Chloride is K-Cl with a molecular mass of 74.55.

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, orange flavor (contains dl-alpha-Tocopherol), propylene glycol, propylparaben, purified water, sodium citrate and sucralose.

Oral Solution 20%: Each 15 mL of solution contains 3 g of potassium chloride, USP and the following inactive ingredients: citric acid anhydrous, FD&C Yellow #6, glycerin, methylparaben, orange flavor (contains dl-alpha-Tocopherol), propylene glycol, propylparaben, purified water, sodium citrate and sucralose.

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 a clear, orange color, orange flavored liquid available in two strengths as follows:

10%: 20 mEq/15 mL oral solution Bottle of 473 mL NDC 59651-959-47

20%: 40 mEq/15 mL oral solution Bottle of 473 mL NDC 59651-960-47

Storage

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Dispense in a tight, light-resistant container as defined in the USP.

PROTECT from LIGHT and FREEZING.

Distributed by: **Aurobindo Pharma USA, Inc.** 279 Princeton-Hightstown Road East Windsor, NJ 08520

Manufactured by:

Aurobindo Pharma Limited

Hyderabad-500 032, India

Issued: October 2024

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mEq per 15 mL (473 mL Bottle Label)

NDC 59651-959-47

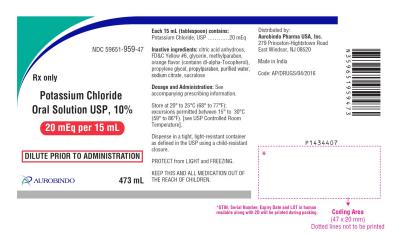
Rx only

Potassium Chloride Oral Solution USP, 10% 20 mEq per 15 mL

DILUTE PRIOR TO ADMINISTRATION

AUROBINDO

473 mL



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 40 mEq per 15 mL (473 mL Bottle Label)

NDC 59651-960-47

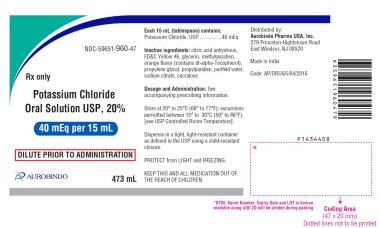
Rx only

Potassium Chloride Oral Solution USP, 20% 40 mEq per 15 mL

DILUTE PRIOR TO ADMINISTRATION

AUROBINDO

473 mL



POTASSIUM CHLORIDE potassium chloride solution							
Product Information							
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Product Inform Product Type Route of Adminis Rotive Ingredie OTASSIUM CHLOR NII:295053K152) INACTIVE Ingred INHYDROUS CITRIC D&C YELLOW NO. LYCERIN (UNII: PDO INTERPLATABEN (U IATER (UNII: 0590)F RISODIUM CITRAT UCRALOSE (UNII: 9 Product Charac olor hape lavor	ent/Active Ingr RIDE (UNII: 66 Idents C ACID (UNII: 46 Idents C ACID (UNII: 477 C6A3C0OX) UNII: AZIBC7H ROL, DL- (UNI L (UNII: 60E) UNII: ZBIX2SC OKOOR) E DIHYDRAT 6KGUQ3Z D4)	ORAL Moiety edient Name OYQ98110) (POTASSIL Ingredient Na XF417D3PSL) VE193A8) III: 7QWA1RIO01) IQ167V3) (10H) TE (UNII: B22547B95K	me Score Size		Basis of Strength	1	Streng 10 meq in 15 mL	
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Product Information of Administrative Ingredies OTASSIUM CHLOR NII:295053K152) Inactive Ingredies DAC YELLOW NO. LYCERIN (UNII: PDO LYCERIN (UNII: PDO LYCERIN (UNII: 059QF ROPYLENE GLYCO ROPYLENARBEN (LYATER (UNII: 059QF RISODIUM CITRAT UCRALOSE (UNII: 9 Product Charact olor hape lavor ontains	ent/Active Ingr IDE (UNII: 66 Idents	ORAL Moiety edient Name OYQ98110) (POTASSIL Ingredient Na XF417D3PSL) VE193A8) III: 7QWA1RIO01) IQ167V3) (10H) TE (UNII: B22547B95K	Score Size Imprint	: Code	Basis of Strength POTASSIUM CHLORIDE		Streng 10 meq in 15 mL Strength	
Product Inform Product Type Route of Adminis Rective Ingredie OTASSIUM CHLOR NII:295053K152) Inactive Ingred ROUTE INGRED	ent/Active Ingr RIDE (UNII: 66 dients C ACID (UNII: H77 6A3COOX) UNII: A28(ACT) UNII: A28(ACT) COKOOR) TE DIHYDRAT 6K6UQ3ZD4) CCTETISTICS Pa 473 mL in 1 B	ORAL Moiety edient Name OYQ98110) (POTASSIL Ingredient Na XF41703PSL) VEI93A8) III: 7QWA1RIO01) OQ167V3) 10H) TE (UNII: B22547B95K ORANGE ORANGE	M CATION - me Score Size Imprint	: Code	Basis of Strength POTASSIUM CHLORIDE		Streng 10 meq in 15 mL	
Product Inform Product Type Route of Adminis Active Ingredie POTASSIUM CHLOR NII:295053K152) INACTIVE Ingred INHYDROUS CITRIC D&C YELLOW NO. ILYCERIN (UNII: 90 INTERNIY (UNII: 90 INTE	ent/Active Ingr RIDE (UNII: 66 dients C ACID (UNII: 677 66A3COX) UNII: 28IRC3F ROL, DL- (UN DL (UNII: 6DC9 UNII: 28IRC3F 6K6UQ3Z D4) CCTETISTICS	ORAL Moiety edient Name OYQ98110) (POTASSIL Ingredient Na XF417D3PSL) VEI93A8) IIIT 7QWA1RIO01) OQ167V3) ORANGE ORANGE ORANGE	M CATION - me Score Size Imprint	: Code	Basis of Strength POTASSIUM CHLORIDE		Streng O meq in 15 mL Strength	
Product Inform Product Type Route of Adminis Rotive Ingredie OTASSIUM CHLOR NII:295053K152) NACTIVE Ingred NHYDROUS CITRIC D&C YELLOW NO. LYCERIN (UNII: PDC LETHYLPARABEN (L LATER (UNII: 05905 RISODIUM CITRAT UCRALOSE (UNII: 9 Product Charac Ingredies I	ent/Active Ingr RIDE (UNII: 66 Idients C ACID (UNII: 66 Idients C ACID (UNII: 67 Idients C ACID	ORAL Moiety edient Name OYQ98110) (POTASSIL Ingredient Na XF417D3PSL) VE193A8) III: 7QWA1RIOO1) Q0167V3) 1OH) E (UNII: B22547B95K ORANGE ORANGE ORANGE OTTLE; Type 0: Not a	M CATION - me Score Size Imprint	: Code	Basis of Strength POTASSIUM CHLORIDE		Streng 10 meq in 15 mL Strength	
Product Information of Administrative Ingredies of Ingred	ent/Active Ingr RIDE (UNII: 66 Idients C ACID (UNII: 66 Idients C ACID (UNII: H77 C6A3C00X) UNII: A2IBC7H C6A3C00X) UNII: A2IBC7H C6A3C00X C7	ORAL Moiety edient Name OYQ98110) (POTASSIL Ingredient Na XF417D3PSL) VE193A8) III: 7QWA1RIOO1) AQ0167V3) 1OH) E (UNII: B22547B95K ORANGE ORANGE ORANGE OTTLE; Type 0: Not a	Score Size Imprint On Combination	**Code Mark(Basis of Strength POTASSIUM CHLORIDE eting Start Date 25	Mari	Streng O meq in 15 mL Strength	
Product Inform Product Type Route of Adminis Rective Ingredie OTASSIUM CHLOR NII:295053K152) Inactive Ingred ROUTE INGRED	ent/Active Ingr RIDE (UNII: 66 Idients C ACID (UNII: 66 Idients C ACID (UNII: H77 C6A3C00X) UNII: A2IBC7H C6A3C00X) UNII: A2IBC7H C6A3C00X C7	ORAL Moiety edient Name OYQ98I10) (POTASSIL Ingredient Na XF417D3PSL) VEI93A8) IIII: III: 7QWA1RIO01) IQ167V3) IOH) TE (UNII: B22547B95K ORANGE ORANGE OTTLE; Type 0: Not a	Score Size Imprint On Combination	**Code Mark(Basis of Strength POTASSIUM CHLORIDE POTASSIUM CHLO	Mari	Streng 10 meq in 15 mL Strength	

Labeler - Aurobindo Pharma Limited (650082092)

Establishment						
Name	Address	ID/FEI	Business Operations			
APL HEALTHCARE LIMITED		650918514	ANALYSIS(59651-959, 59651-960), MANUFACTURE(59651-959, 59651-960)			

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