

POTASSIUM CHLORIDE- potassium chloride solution

MICRO LABS LIMITED

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 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 (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 Saptalis Pharmaceuticals, LLC at 1-833-727-8254 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 (8.6)
- Renal Impairment: Initiate therapy at the low end of the dosing range (8.7)

Revised: 3/2023

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FULL PRESCRIBING INFORMATION

1 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.

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 oral 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 ranges 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 oral solution 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.
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 1,000 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 colorless crystals. It is freely soluble in water and practically insoluble in ethanol. Chemically, potassium chloride, USP 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 No. 6, glycerin, methylparaben, natural & artificial 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 No. 6, glycerin, methylparaben, natural & artificial orange flavor, propylene glycol, propylparaben, purified water, sodium citrate dihydrate, 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 liquid with citrus aroma, available in two strengths as follows:

10%: 20 mEq/15 mL oral solution

NDC# 42571-357-07 Bottle with child-resistant cap of 473 mL

20%: 40 mEq/15 mL oral solution

NDC# 42571-358-07 Bottle with child-resistant cap of 473 mL

Storage

Store at 20° to 25°C (68° to 77°F), with 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. Keep tightly closed.

PROTECT from LIGHT and FREEZING.

Rx only

Distributed by:

Micro Labs USA, Inc.

Somerset, NJ 08873

Manufactured by:

Saptalis Pharmaceuticals, LLC

Hauppauge, NY 11788

03/23-R2

PPM-0012

Package/Label Display Panel

NDC 42571-357-07

Potassium Chloride Oral Solution USP, 10%

20 mEq per 15 mL

DILUTE PRIOR TO ADMINISTRATION

Rx only

473 mL

Each 15 mL (tablespoon) contains:
Potassium chloride, USP20 mEq

Inactive ingredients: citric acid anhydrous, FD&C Yellow No. 6, glycerin, methylparaben, natural & artificial orange flavor, propylene glycol, propylparaben, purified water, sodium citrate dihydrate, sucralose.

Usual Dosage: See accompanying prescribing information.

Store at 20° to 25°C (68° to 77°F), with excursions permitted between 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature]. Protect from Light and Freezing.

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

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

NDC 42571-357-07

Potassium Chloride Oral Solution USP, 10%

20 mEq per 15 mL

DILUTE PRIOR TO ADMINISTRATION

Rx only

473 mL

SAPTALIS

MICRO LABS

MADE IN USA

LAM-0011 03/23-R2

Distributed by:
Micro Labs USA, Inc.
Somerset, NJ 08873

Manufactured by:
Saptalis Pharmaceuticals, LLC
Hawthorne, NJ 07033

SPACE FOR SERIALIZATION

Unreserved area for batch details
LOT: XXXXXXX
EXP: MM/YYYY
will be printed online

OR

Unreserved area as per DGP
EXP: MM/YYYY
LOT: XXXXXXX
will be printed online

* The batch coding given as per regular practice. Once after the Plant is ready for DGP printing, the batch coding details will be revised as mentioned above to adhere to the Directorate General of Foreign Trade Notification

Package/Label Display Panel

NDC 42571-358-07

Potassium Chloride Oral Solution USP, 20%

40 mEq per 15 mL

DILUTE PRIOR TO ADMINISTRATION

Rx only

473 mL

Each 15 mL (tablespoon) contains:
Potassium chloride, USP40 mEq

Inactive Ingredients: citric acid anhydrous, FD&C Yellow No. 6, glycerin, methylparaben, natural & artificial orange flavor, propylene glycol, propylparaben, purified water, sodium citrate dihydrate, sucralose.

Usual Dosage: See accompanying prescribing information.

Store at 20° to 25°C (68° to 77°F), with excursions permitted between 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature]. Protect from Light and Freezing.

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

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

NDC 42571-358-07

Potassium Chloride Oral Solution USP, 20%

40 mEq per 15 mL

DILUTE PRIOR TO ADMINISTRATION

Rx only

473 mL

SAPTALIS

MICRO LABS

LAM-0012 03/23-R2

Distributed by:
Micro Labs USA, Inc.
Somerset, NJ 08873

Manufactured by:
Saptalis Pharmaceuticals, LLC
Hauppauge, NY 11788

MADE IN USA

SPACE FOR
SERIALIZATION

Unreserved area for batch details
LOT: XXXXXXXX
EXP: MM/YYYY
will be printed online

OR

Unreserved area as per DGFT
2D Matrix
LOT: 010 XXXXXXXX
EXP: 01/20180000
LOT: 001 XXXXXXXX
EXP: 01/20180000
will be printed online

* The batch coding given as per regular practice. Once after the Plant is ready for DGFT printing, the batch coding details will be revised as mentioned above to adhere the Directorate General of Foreign Trade Notification

POTASSIUM CHLORIDE

potassium chloride solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42571-357
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	1.5 g in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

ORANGE (UNII: 5EVU04N5QU)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
Product Characteristics				
Color		orange	Score	
Shape			Size	
Flavor		ORANGE	Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42571-357-07	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2021	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA211648	05/21/2021	

POTASSIUM CHLORIDE			
potassium chloride solution			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42571-358
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)		POTASSIUM CHLORIDE	3 g in 15 mL
Inactive Ingredients			
Ingredient Name			Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
GLYCERIN (UNII: PDC6A3C0OX)			

METHYLPARABEN (UNII: A2I8C7HI9T)	
ORANGE (UNII: 5EVU04N5QU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42571-358-07	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211648	05/21/2021	

Labeler - MICRO LABS LIMITED (862174955)

Registrant - Saptalis Pharmaceuticals, LLC (080145868)

Establishment

Name	Address	ID/FEI	Business Operations
Saptalis Pharmaceuticals, LLC		080145868	manufacture(42571-357, 42571-358)