POKONZA POTASSIUM CHLORIDE- potassium chloride liquid
Carwin Pharmaceutical Associates, LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use POKONZA® safely and effectively. See full prescribing information for POKONZA®.
POKONZA® (Potassium chloride oral solution)
Initial U.S. Approval: 1948

INDICATIONS AND USAGE

POKONZA® (Potassium Chloride Oral Solution, USP) 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 mEq to 100 mEq/day orally 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 mEq to 4 mEq/kg/day orally 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 orally per day (2.2)
- Pediatric patients aged birth to 16 years old: typical dose is 1 mEq/kg/day orally. Do not exceed 3 mEq/kg/day (2.3)

DOSAGE FORMS AND STRENGTHS

- Oral Solution: 5%; 10 mEq/15mL 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 Carwin Pharmaceutical Associates at 1-844-700-5011 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: 1/2026

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

POKONZA® (Potassium Chloride Oral Solution, USP) 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 POKONZA® with at least 4 ounces of cold water *[see Warnings and Precautions (5.1)]*. Instruct patients or caregivers to use an oral dosing cup or syringe to correctly measure the prescribed amount of medication. Inform patients that oral dosing cups or syringes may be obtained from their pharmacy.

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 mEq to 100 mEq orally. 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 orally. 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 mEq/kg/day to 4 mEq/kg/day orally in divided doses; do not exceed as a single dose 1 mEq/kg or 40 mEq orally, whichever is lower; maximum daily doses should not exceed 100 mEq orally. 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 orally. Do not exceed 3 mEq/kg/day.

3 DOSAGE FORMS AND STRENGTHS

Oral Solution 5%: 10 mEq/15 mL

4 CONTRAINDICATIONS

POKONZA® 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 POKONZA® 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 POKONZA® 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 POKONZA® have been demonstrated in children with diarrhea and malnutrition from birth to 16 years.

8.5 Geriatric Use

Clinical studies of POKONZA® 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 mEq/L 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 mEq/L 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 is a white crystalline or colorless solid. It is soluble in water and slightly soluble in alcohol. Chemically, Potassium Chloride is K-Cl with a molecular mass of 74.55.

Oral Solution: 5%: 10 mEq/15 mL of solution contains 0.75 g of potassium chloride, USP and the following inactive ingredients: citric acid anhydrous, FD&C Yellow #6, glycerin, natural/ artificial orange flavor, purified water, sodium benzoate, 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 mEq to 160 mEq per

liter. The normal adult plasma concentration is 3.5 mEq 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 mEq 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

POKONZA® (Potassium Chloride Oral Solution, USP) is an orange solution available in one strength as follows:

5%: 10 mEq/15mL oral solution
NDC# 15370-307-04 Bottle of 118 mL
NDC# 15370-307-08 Bottle of 237 mL
NDC# 15370-307-16 Bottle of 473 mL

Storage

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 and FREEZING.

Rx only

Distributed by:
Carwin Pharmaceutical Associates, LLC.
Hazlet, NJ 07730

Revised: 11/2025

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

NDC 15370-307-04

POKONZA®
(Potassium Chloride

Oral Solution, USP, 5%)

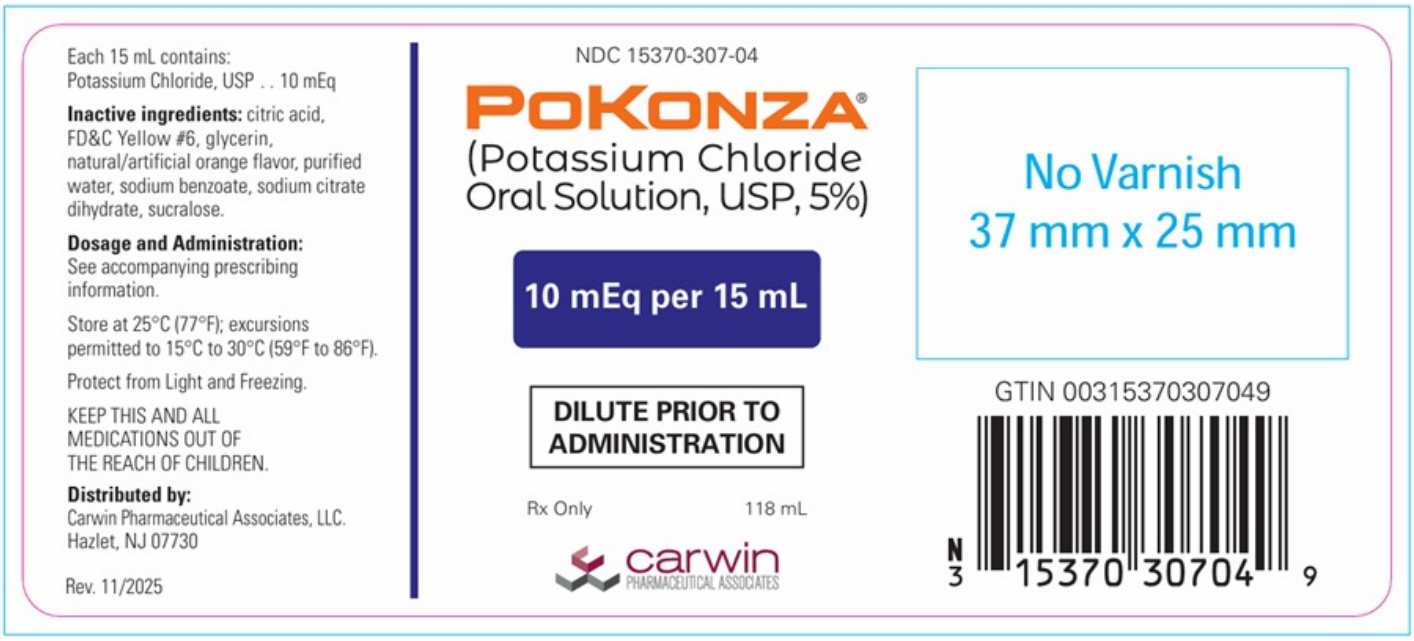
10 mEq per 15 mL

DILUTE PRIOR TO
ADMINISTRATION

Rx Only

118 mL

carwin
PHARMACEUTICAL ASSOCIATES



POKONZA POTASSIUM CHLORIDE

potassium chloride liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:15370-307
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	10 meq in 15 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	

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:15370-307-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/14/2026	
2	NDC:15370-307-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/14/2026	
3	NDC:15370-307-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/14/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA206814	01/14/2026	

Labeler - Carwin Pharmaceutical Associates, LLC (079217215)

Revised: 1/2026 Carwin Pharmaceutical Associates, LLC