POTASSIUM CHLORIDE- potassium chloride solution
Pharmaceutical Associates, Inc.

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 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 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 40-100 mEq/day in 2-5 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: 2-4 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 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 Pharmaceutical Associates, Inc. at 1-800-845-8210 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

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

Potassium Chloride 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 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.

8.3 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 16 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 (6.5-8.0 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 (9-12 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 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, berry citrus flavor, potassium sorbate, purified water and sodium saccharin.

Oral Solution 20%: Each 15 mL of solution contains 3.0 g of potassium chloride, USP and the following inactive ingredients: glycerin, potassium sorbate, purified water and sodium saccharin.

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 10% (20 mEq/15 mL) is a berry citrus flavored, orange-colored solution available as follows:

NDC 0121-1680-16:	16 fl oz (473 mL) bottle
NDC 0121-1680-15:	15 mL unit dose cup, in a tray of ten cups.
NDC 0121-2520-30:	30 mL unit dose cup, in a tray of ten cups.

Potassium Chloride Oral Solution, USP 20% (40 mEq/15 mL) is an unflavored, clear, dye free/sugar free solution available as follows:

NDC 0121-0841-15:	15 mL unit dose cup, in a tray of ten cups.

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].

PROTECT from LIGHT and FREEZING.

Rx Only

R05/19

MANUFACTURED BY

Pharmaceutical
Associates, Inc.
Greenville, SC 29605
www.paipharma.com

PRINCIPAL DISPLAY PANEL - 16 fl oz (473 mL)

Delivers **16 fl oz (473 mL)**
NDC 0121-1680-16

P otassium C hloride
O ral S olution, USP 10%

20 mEq per 15 mL

DILUTE PRIOR TO ADMINISTRATION

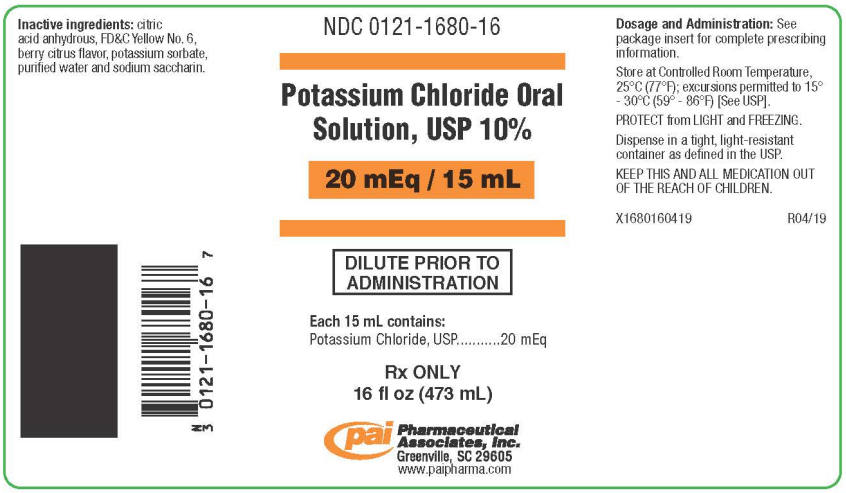
Rx ONLY

FOR INSTITUTIONAL USE ONLY

PHARMACEUTICAL ASSOCIATES, INC.
GREENVILLE, SC 29605

SEE INSERT

X1680160419



PRINCIPAL DISPLAY PANEL - 15 mL Cup Label

Delivers **15 mL**
NDC 0121-1680-15

P otassium C hloride
O ral S olution, USP 10%

20 mEq per 15 mL

DILUTE PRIOR TO ADMINISTRATION

Rx ONLY

FOR INSTITUTIONAL USE ONLY

PHARMACEUTICAL ASSOCIATES, INC.
GREENVILLE, SC 29605

SEE INSERT

A0840150418

PRINCIPAL DISPLAY PANEL - 30 mL Cup Label

Delivers **30 mL**
NDC 0121-2520-30

P otassium C hloride
O ral S olution, USP 10%

40 mEq per 30 mL

DILUTE PRIOR TO ADMINISTRATION

Rx ONLY

FOR INSTITUTIONAL USE ONLY

PHARMACEUTICAL ASSOCIATES, INC.

GREENVILLE, SC 29605

SEE INSERT

A0840300418

PRINCIPAL DISPLAY PANEL - 15 mL Cup Label - 20%

Delivers **15 mL**
NDC 0121-0841-15

P otassium C hloride
O ral S olution, USP 20%

Dye Free / Sugar Free

40 mEq per 15 mL

DILUTE PRIOR TO ADMINISTRATION

Rx ONLY

FOR INSTITUTIONAL USE ONLY

PHARMACEUTICAL ASSOCIATES, INC.
GREENVILLE, SC 29605

SEE INSERT

A0841151018

POTASSIUM CHLORIDE

potassium chloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0121-1680
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)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics			
Color	orange	**Score**	
Shape		**Size**	
Flavor	BERRY, CITRUS	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-1680-15	10 in 1 CASE	04/02/2019	
1		10 in 1 TRAY		
1		15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-1680-80	8 in 1 CASE	04/20/2020	
2		10 in 1 TRAY		
2		15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:0121-1680-30	3 in 1 CASE	04/20/2020	
3		10 in 1 TRAY		
3		15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
4	NDC:0121-1680-50	5 in 1 CASE	04/20/2020	
4		10 in 1 TRAY		
4		15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
5	NDC:0121-1680-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/13/2019	
6	NDC:0121-1680-00	10 in 1 CASE	04/19/2019	
6		10 in 1 TRAY		
6		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	ANDA210766	04/02/2019	

POTASSIUM CHLORIDE

potassium chloride solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0121-2520
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	40 meq in 30 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics			
Color	orange	**Score**	
Shape		**Size**	
Flavor	BERRY, CITRUS	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0121-2520-30	10 in 1 CASE	04/02/2019	
1		10 in 1 TRAY		
1		30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-2520-00	10 in 1 CASE	04/02/2019	
2		10 in 1 TRAY		
2		30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:0121-2520-40	4 in 1 CASE	04/02/2019	
3		10 in 1 TRAY		
3		30 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	ANDA210766	04/02/2019	

POTASSIUM CHLORIDE

potassium chloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0121-0841
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	40 meq in 15 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0121-0841-15	10 in 1 CASE	04/02/2019	
1		10 in 1 TRAY		
1		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	ANDA210766	04/02/2019	

Labeler - Pharmaceutical Associates, Inc. (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	manufacture(0121-1680, 0121-2520, 0121-0841)

Revised: 2/2020 Pharmaceutical Associates, Inc.