POTASSIUM CHLORIDE- potassium chloride liquid
Pack Pharmaceuticals LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Potassium Chloride Oral Solution, USP

INACTIVE INGREDIENTS

citric acid, D&C Red #33, FD&C Red #40, glycerin, purified water, sodium benzoate, sodium saccharin, sorbitol solution, wild cherry flavor.

INDICATION

For treatment of patient with hypokalemia, with or without metabolic alkalosis, in digitalis intoxication.

DIRECTION

To minimize gastrointestinal irritation, patients must follow direction regarding dilution. Each tablespoonful (15mL) should be diluted with three (3) fluid ounce or more of water or other liquid.

USUAL ADULT DOSE

One (1) tablespoonful (15mL) twice daily (after morning or evening meals) supplies 40 mEq of potassium.

WARNINGS

Discontinue immediately if abdominal pain, distension, nausea, vomiting or gastrointestinal bleeding occurs. CONTRAINDICATED in the presence of dehydration or impaired kidney function. Potassium intoxication causes electrocardiographic abnormalities, flaccid paralysis of the skeletal muscles, paresthesias of the extremeties, listlessness, mental confusion, weakness and heaviness of the legs, fall in blood pressure, cardiac arrhythmias. Frequent checks of the clinical status of the patient, and periodic ECG and/or serum potassium levels should be made. Potassium intensifies the symptoms of myotonia congenita.

DRUG INTERACTION

Interaction with Potassium Sparing Diuretics: Hypokalemia should not be treated by the concomitant administration of potassium salts and potassium-sparing diuretics (e.g., spironolactone, triamterene or amiloride) since the simultaneous administration of these agents can produce severe hyperkalemia. Interaction with ACE inhibitors: Angiotensin converting enzyme (ACE) inhibitors (e.g., captopril, enlapril) will produce some potassium retention by inhibiting aldosterone production. Potassium supplements should be given to patients receiving ACE inhibitors only with close monitoring.

TOXICITY

Hyperkalemia, when detected, must be treated immediately because lethal levels can be reached in a few hours.

Dispense in tight, light-resistant container as defined in USP/NF.

Store at 20 - 25°C (66 to 77°F). Avoid Freezing.

QUESTION

Adverse Drug Event: Call (866) 562-4597

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 16571-303-16
TAMPER EVIDENT

Potassium Chloride
Oral Solution, USP

10% Cherry Flavored
Sugar Free

Rx only

40 m Eq. Potassium per 30mL

Replacement therapy for
POTASSIUM-Deficiency States
To be used for oral administration only.

TAMPER-EVIDENT: Do not use this product
if inner foil seal over the mouth of the
bottle is cut, torn, broken or missing.

Manufactured by:
Bio-Pharm, Incorporated Levittown, PA 19057
Distributed by:
PACK™
Pharmaceuticals
PACK Pharmaceuticals, LLC Buffalo Grove, IL 60089

ONE PINT (473 mL)

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unvarnished area

Rev. 0813

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N 3 16571 30316 8

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Distributed by:

PACK™ Pharmaceuticals
PACK Pharmaceuticals, LLC Buffalo Grove, IL 60089

ONE PINT (473 mL)

POTASSIUM CHLORIDE

potassium chloride liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16571-303
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Potassium Chloride (UNII: 660YQ98I10) (Potassium Cation - UNII:295O53K152, Chloride Ion -	Potassium	40 meq

UNII:Q32ZN48698)	Chloride	in 30 mL

Inactive Ingredients

Ingredient Name	Strength
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sorbitol (UNII: 506T60A25R)	
Glycerin (UNII: PDC6A3C0OX)	
Cherry (UNII: BUC5I9595W)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
Water (UNII: 059QF0KO0R)	

Product Characteristics

Color	PINK	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16571-303-16	473 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		09/23/2013	

Labeler - Pack Pharmaceuticals LLC (614823875)

Establishment

Name	Address	ID/FEI	Business Operations
Bio-Pharm, Inc.		801652546	MANUFACTURE(16571-303) , ANALYSIS(16571-303) , PACK(16571-303) , LABEL(16571-303)

Revised: 9/2013 Pack Pharmaceuticals LLC