POTASSIUM CHLORIDE- potassium chloride tablet, film coated, extended release
PD-Rx Pharmaceuticals, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use POTASSIUM CHLORIDE EXTENDED-RELEASE TABLETS safely and effectively. See full prescribing information for POTASSIUM CHLORIDE EXTENDED-RELEASE TABLETS.

POTASSIUM CHLORIDE extended-release tablets, for oral use
Initial U.S. Approval: 1948

INDICATIONS AND USAGE

Potassium chloride extended-release tablets are 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 is insufficient. (1)

DOSAGE AND ADMINISTRATION

- Monitor serum potassium and adjust dosages accordingly (2.1)
- If serum potassium concentration is less than 2.5 mEq/L, use intravenous potassium instead of oral supplementation (2.1)
- Take with meals and with a glass of water or other liquid. Swallow tablets whole. (2.1)
- Treatment of hypokalemia:Typical dose range is 40-100 mEq per day in divided doses. Limit doses to 20 mEq per dose. (2.2)
- Prevention of hypokalemia:Typical dose is 20 mEq per day (2.2)

DOSAGE FORMS AND STRENGTHS

- 10 mEq (750mg) oral tablets (3)
- 15 mEq (1125 mg) oral tablet (3)
- 20 mEq (1500 mg) oral tablets (3)

CONTRAINDICATIONS

- Concomitant use with triamterene and amiloride (4, 7.1)

WARNINGS AND PRECAUTIONS

- Gastrointestinal Adverse Reactions: Can produce ulcerative and/or stenotic lesions of the gastrointestinal tract, particularly when in prolonged contact with the gastrointestinal mucosa. 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 Advagen Pharma Ltd, at 866-488-0312 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Renin-angiotensin-aldosterone system 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)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 1/2025

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 extended-release tablets are 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 is insufficient.

2 DOSAGE AND ADMINISTRATION

2.1 Monitoring and Administration

If serum potassium concentration is less than 2.5 mEq/L, use intravenous potassium instead of oral supplementation.

Monitoring

Monitor serum potassium and adjust the dose based on serum potassium level. Monitor serum potassium periodically during maintenance therapy to ensure potassium remains in desired range.

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

Take potassium chloride extended-release tablets with meals and with a glass of water or other liquid. Do not take on an empty stomach because of its potential for gastric irritation *[see Warnings and Precautions (5.1)]* .

Swallow tablets whole without crushing, chewing or sucking.

2.2 Dosing

Dosage must be adjusted to the individual needs of each patient. Dosages greater than 20 mEq per day should be divided such that no more than 20 mEq is given in a single dose.

Treatment of hypokalemia:Typical dose range is 40-100 mEq per day.

Prevention of hypokalemia:Typical dose is 20 mEq per day.

3 DOSAGE FORMS AND STRENGTHS

- 10 mEq (750mg) : White to off-white, film coated, capsule shaped tablet, debossed with “111” on one side and” Λ” on other side.
- 15 mEq (1125 mg): Yellow colored, Film coated, Capsule shaped tablet, debossed with “E41” on one side and “Λ” on other side.
- 20 mEq (1500 mg): White to off-white, film coated, capsule shaped tablet, debossed with “112” on one side and” Λ” on other side.

4 CONTRAINDICATIONS

Potassium chloride is contraindicated in patients on triamterene or amiloride.

5 WARNINGS AND PRECAUTIONS

5.1 Gastrointestinal Adverse Reactions

Solid oral dosage forms of potassium chloride can produce ulcerative and/or stenotic lesions of the gastrointestinal tract, particularly when the drug remains in contact with

the gastrointestinal mucosa for a prolonged period of time. Consider the use of liquid potassium in patients with dysphagia, swallowing disorders, or severe gastrointestinal motility disorders.

If severe vomiting, abdominal pain, distention, or gastrointestinal bleeding occurs, discontinue potassium chloride extended-release tablets and consider possibility of ulceration, obstruction or perforation.

Potassium chloride extended-release tablets should not be taken on an empty stomach because of its potential for gastric irritation *[see Dosage and Administration (2.1)]* .

6 ADVERSE REACTIONS

The following adverse reactions have been identified with use of oral potassium salts. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The most common adverse reactions to oral potassium salts are nausea, vomiting, flatulence, abdominal pain/discomfort, and diarrhea.

There have been reports of hyperkalemia and of upper and lower gastrointestinal conditions including obstruction, bleeding, ulceration, perforation *[see Warnings and Precautions (5.1) and Overdosage (10)]* .

Skin rash has been reported rarely.

7 DRUG INTERACTIONS

7.1 Triamterene and Amiloride

Use with triamterene or amiloride can produce severe hyperkalemia. Avoid concomitant use *[see Contraindications (4)]* .

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

Nonsteroidal anti-inflammatory drugs (NSAIDs) may produce potassium retention by reducing renal synthesis of prostaglandin E and impairing the renin-angiotensin system. Closely monitor potassium in patients receiving concomitant NSAID therapy.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no human data related to use of potassium chloride extended-release tablets during pregnancy, and animal reproduction 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 2-4% and 15-20%, 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

Safety and effectiveness of potassium chloride extended-release tablets in children have not been established.

8.5 Geriatric Use

Clinical studies of potassium chloride extended-release tablets 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

Doses of potassium in patients with cirrhosis produce a larger increase in potassium levels compared to the response in normal patients. Based on published literature, the baseline corrected serum concentrations of potassium measured over 3 hours after administration in cirrhotic subjects who received an oral potassium load rose to approximately twice that of normal subjects who received the same load. Patients with cirrhosis should usually be started at the low end of the dosing range, and the serum potassium level should be monitored frequently.

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 RAAS inhibitors or NSAIDs, should usually be started at the low end of the dosing range because of the potential for development of hyperkalemia *[see Drug Interactions (7.2, 7.3)]* . 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, potentially fatal hyperkalemia can result *[see Contraindications (4)* and *Warnings and Precautions (5.1)]* .

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 P-waves, depression of S-T segments, and prolongation of the QT intervals). 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 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.

The extended release feature means that absorption and toxic effects may be delayed for hours. Consider standard measures to remove any unabsorbed drug.

11 DESCRIPTION

Potassium chloride extended-release tablets are a solid oral dosage form of potassium chloride containing 750 mg, 1125 mg and 1500 mg of potassium chloride, USP, equivalent to 10 mEq, 15 mEq and 20 mEq of potassium, respectively, in a film-coated matrix tablet.

The chemical name is potassium chloride, and the structural formula is KCl. Potassium chloride, USP, occurs as a white, granular powder or as colorless crystals. It is odorless

and has a saline taste. Its solutions are neutral to litmus. It is freely soluble in water and insoluble in alcohol.

The 10 mEq, 15 mEq and 20 mEq tablets contain colloidal silicon dioxide, magnesium stearate, paraffin, polyethylene glycol, polyvinyl acetate, povidone, sodium lauryl sulphate, polyvinyl alcohol, talc, titanium dioxide, triethyl citrate, D&C yellow # 10 (for 15 mEq) and FD&C yellow # 6 (for 15 mEq).

FDA approved dissolution test specifications and assay sample preparation method differs from USP.

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 impulse; 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.

12.2 Pharmacokinetics

Specific Populations

Cirrhotics

Based on published literature, the baseline corrected serum concentrations of potassium measured over 3 hours after administration in cirrhotic subjects who received an oral potassium load rose to approximately twice that of normal subjects who received the same load *[see Use in Specific Populations (8.6)]* .

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, mutagenicity and fertility studies in animals have not been performed. Potassium is a normal dietary constituent.

16 HOW SUPPLIED/STORAGE AND HANDLING

Potassium chloride extended-release tablets, USP contain 1500 mg of potassium chloride (equivalent to 20 mEq of potassium, respectively). Potassium chloride extended-release tablets are provided as film coated tablets in following strengths and package configurations:

Strength	Description	Bottle Count	NDC #
20 mEq (1500 mg)	White to off-white, film coated, capsule shaped tablet, debossed with “112” on one side and” Λ” on other side	500	72789-504-82

Recommended Storage

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

17 PATIENT COUNSELING INFORMATION

- Inform patients to take each dose with meals and with a full glass of water or other liquid, and to not crush, chew, or suck the tablets.
- Advise patients to seek medical attention if tarry stools or other evidence of gastrointestinal bleeding is noticed.
- Inform patients that the wax tablet is not absorbed and may be excreted intact in the stool. If the patient observes this, it is not an indication of lack of effect.

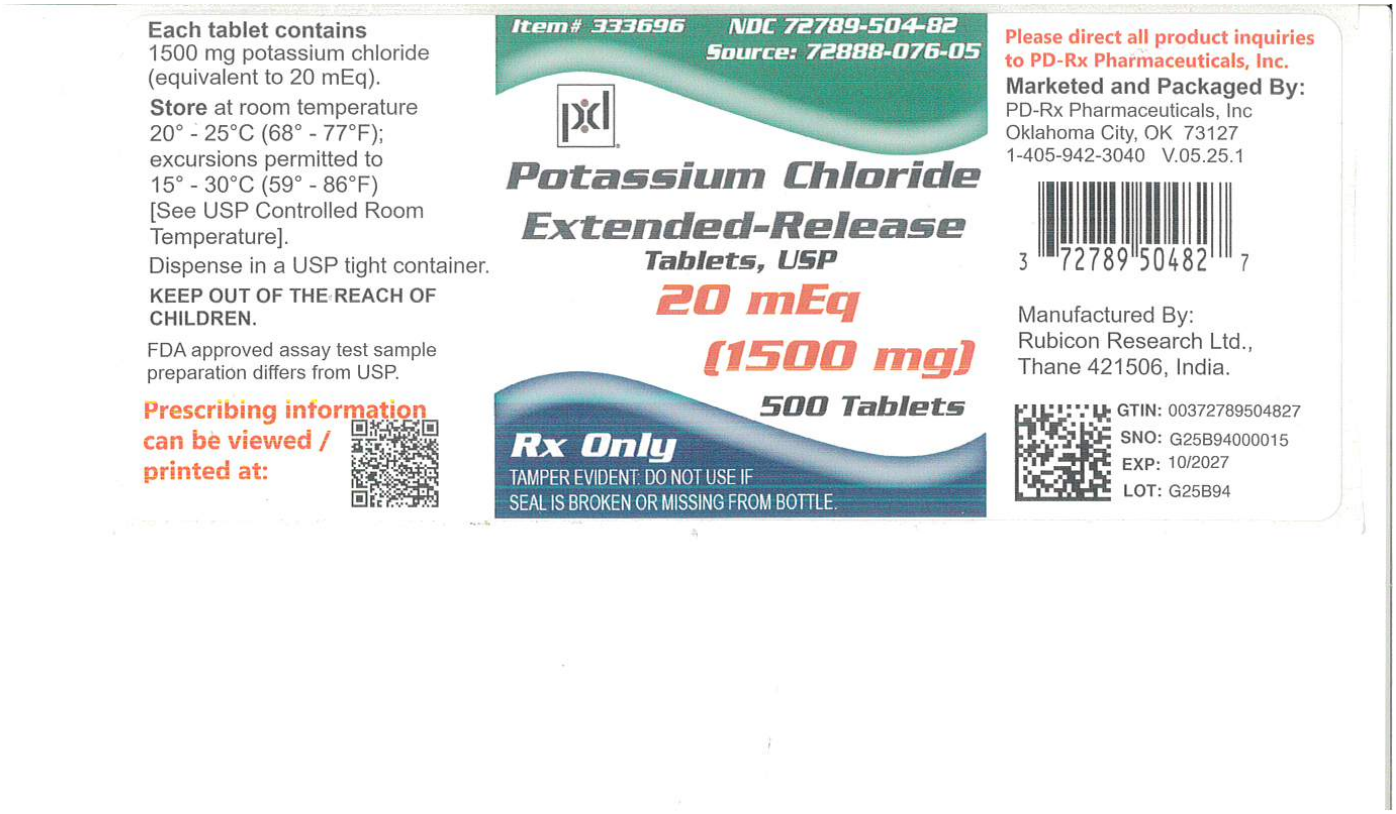
Distributed By:
Advagen Pharma Ltd.,
East Windsor, NJ 08520, USA.

Manufactured by:
Rubicon Research Pvt. Ltd.,
Thane, 421506 India.

Rev. 01/2025

PRINCIPAL DISPLAY PANEL

Potassium chloride extended-release tablets, USP 1500mg label



POTASSIUM CHLORIDE

potassium chloride tablet, film coated, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72789-504(NDC:72888-076)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	1500 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PARAFFIN (UNII: I9O0E3H2ZE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ACETATE (UNII: 32K497ZK2U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	white (White to off-white)	**Score**	no score
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	UpArrowhead;112
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72789-504-82	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215725	07/25/2022	

Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack(72789-504)

Revised: 7/2025 PD-Rx Pharmaceuticals, Inc.