POTASSIUM CHLORIDE- potassium chloride tablet, extended release
Direct_Rx

POTASSIUM CHLORIDE

DESCRIPTION SECTION

Potassium Chloride Extended-release Tablets, USP are a solid oral dosage form of potassium chloride. Each contains 600 mg or 750 mg of potassium chloride equivalent to 8 mEq or 10 mEq of potassium in a wax matrix tablet.

Potassium Chloride Extended-release Tablets, USP are an electrolyte replenisher. The chemical name is potassium chloride, and the structural formula is KCl. Potassium chloride, USP is a white, granular powder or 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.

Inactive Ingredients: Hydrogenated Vegetable Oil Type 1, Ethylcellulose (10cP), Ethylcellulose (100cP), Silicon Dioxide, Talc, Magnesium Stearate. The 600 mg tablets also contain Polyvinyl Alcohol, Titanium dioxide, Macrogol / PEG, Talc, FD&C Blue #1 / Brilliant Blue FCF Aluminum Lake, FD&C Blue #2 / Indigo Carmine Al 3% - 5% and the 750 mg tablets also contain of Polyvinyl Alcohol, Titanium dioxide, Macrogol / PEG, Talc, FD&C Yellow #5 / Tartrazine Aluminum Lake and FD&C Yellow #6 / Sunset Yellow FCF Aluminum Lake.

"FDA approved dissolution test specifications differ from USP." and "FDA approved acceptance criteria for assay differs from USP test."

CLINICAL PHARMACOLOGY SECTION

12.1 Mechanism of Action

The potassium ion 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

The potassium chloride in Potassium Chloride extended-release is completely absorbed before it leaves the small intestine. The wax matrix is not absorbed and is excreted in the feces; in some instances the empty matrices may be noticeable in the stool. When the bioavailability of the potassium ion from the Potassium Chloride extended-release is compared to that of a true solution the extent of absorption is similar.

The extended-release properties of Potassium Chloride extended-release are demonstrated by the finding that a significant increase in time is required for renal excretion of the first 50% of the Potassium Chloride extended-release dose as compared to the solution.

Increased urinary potassium excretion is first observed 1 hour after administration of Potassium Chloride extended-release, reaches a peak at approximately 4 hours, and extends up to 8 hours. Mean daily steady-state plasma levels of potassium following daily administration of Potassium Chloride extended-release tablets cannot be distinguished from those following administration of potassium chloride solution or from control plasma levels of potassium ion.

Specific Populations

Cirrhotics

Based on publish 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.

In rare circumstances, (e.g., patients with renal tubular acidosis) potassium depletion may be associated with metabolic acidosis and hyperchloremia. In such patients potassium replacement should be accomplished with potassium salts other than the chloride, such as potassium bicarbonate, potassium citrate, potassium acetate, or potassium gluconate.

INDICATIONS & USAGE SECTION

BECAUSE OF REPORTS OF INTESTINAL AND GASTRIC ULCERATION AND BLEEDING WITH CONTROLLED-RELEASE POTASSIUM CHLORIDE PREPARATIONS, THESE DRUGS SHOULD BE RESERVED FOR THOSE PATIENTS WHO CANNOT TOLERATE OR REFUSE TO TAKE LIQUID OR EFFERVESCENT POTASSIUM PREPARATIONS, OR FOR PATIENTS WITH WHOM THERE IS A PROBLEM OF COMPLIANCE WITH THESE PREPARATIONS.

1. For the treatment of patients with hypokalemia with or without metabolic alkalosis, in digitalis intoxication, and in patients with hypokalemic familial periodic paralysis. If hypokalemia is the result of diuretic therapy, consideration should be given to the use of a lower dose of diuretic, which may be sufficient without leading to hypokalemia.
2. For the prevention of hypokalemia in patients who would be at particular risk if hypokalemia were to develop, e.g., digitalized patients or patients with significant cardiac arrhythmias.

The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern, and when low doses of the diuretic are used. Serum potassium should be checked periodically, however, and, if hypokalemia occurs, dietary supplementation with potassium-containing foods may be adequate to control milder cases. In more severe cases and if dose adjustment of the diuretic is ineffective or unwarranted supplementation with potassium salts may be indicated.

CONTRAINDICATIONS SECTION

Potassium chloride is contraindicated in patients on triamterene and amiloride.

ADVERSE REACTIONS SECTION

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 hyperkalemia and of upper and lower gastrointestinal condition including obstruction, bleeding, ulceration, perforation.

Skin rash has been reported rarely.

OVERDOSAGE SECTION

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 and WARNINGS].

It is important to recognize that 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-wave, 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:

Elimination of foods and medications containing potassium and of any agents with potassium-sparing properties.
Intravenous administration of 300 to 500 mL/hr of 10% dextrose solution containing 10 to 20 units of crystalline insulin per 1,000 mL.
Correction of acidosis, if present, with intravenous sodium bicarbonate.
Use of exchange resins, hemodialysis or peritoneal dialysis.

In treating hyperkalemia, it should be recalled that 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.

DOSAGE & ADMINISTRATION SECTION

2.1 Administration and Monitoring

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

Monitoring

Monitor serum potassium and adjust dosages accordingly. 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, USP with meals and with a glass of water or other liquid. Do not take Potassium Chloride Extended-release Tablets, USP 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 40 mEq per day should be divided such that no more than 40 mEq is given in a single dose.

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

Maintenance or Prophylaxis: Typical dose range is 20 mEq per day.

HOW SUPPLIED SECTION

Potassium Chloride Extended Release Tablets, USP 8 mEq [600mg] are blue colored, circular biconvex film coated tablets plain on one side and debossed "P8" on another side.

600 mg potassium chloride (equivalent to 8 mEq) are available in bottles of 100 (NDC 64380-860-06), bottles of 500 (NDC 64380-860-07), bottles of 1000 (NDC 64380-860-08).

Potassium Chloride Extended Release Tablets, USP 10 mEq [750mg] are yellow colored, circular biconvex film coated tablets plain on one side and debossed "P10" on another side.

750 mg potassium chloride (equivalent to 10 mEq) are available in bottles of 100 (NDC 64380-861-06), bottles of 500 (NDC 64380-861-07), bottles of 1000 (NDC 64380-861-08).

Store at 25ºC (77ºF) [See USP Controlled Room Temperature]. Protect from light and moisture.

Dispense in a tight container as defined in the USP with a child resistant closure.

Potassium Chloride Extended Release Tablets, USP are supplied as:

Potassium Chloride Extended Release Tablets, USP 8 mEq [600mg] are blue colored, circular biconvex film coated tablets plain on one side and debossed "P8" on another side.

Potassium Chloride Extended Release Tablets, USP 10 mEq [750mg] are yellow colored, circular biconvex film coated tablets plain on one side and debossed "P10" on another side.

5.1 Gastrointestinal Adverse Reactions

Solid oral dosage forms of potassium chloride can produce ulcerative and/or stenotic lesions of the gastrointestinal tract, particularly if the drug maintains contact with the gastrointestinal mucosa for prolonged periods. 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 K-TAB and consider possibility of ulceration, obstruction or perforation.

K-TAB should not be taken on an empty stomach because of its potential for gastric irritation [see Dosage and Administration (2.1)].

7.1 Triamterene or amiloride

Use with triamterene or amiloride can produce severe hyperkalemia. Concomitant use is contraindicated [see Contraindications (4)].

7.2 Renin-angiotensin-aldosterone 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 on concomitant RAAS inhibitors.

7.3 Nonsteroidal Anti-inflammatory Drugs (NSAIDs)

NSAIDS may produce potassium retention by reducing renal synthesis of prostaglandin E and imparing the renin-angiotensin system. Closely monitor potassium in patients on concomitant NSAIDs.

8.1 Pregnancy

Risk Summary

There are no human data related to use of Potassium Chloride Extended-release Tablets, USP 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 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.

8.4 Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

8.5 Geriatric Use

Clinical studies of Potassium Chloride extended-release 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

Based on publish 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 [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 [see Warnings and Precautions (5.2)]. 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.

Potassium Chloride Extended-Release Tablets, USP 750 mg contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

13.1 Carcinogenesis, Mutagenesis, and Impairment of Fertility

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

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. Inform patients that the wax matrix is not absorbed and is excreted in the feces; in some instances the empty matrices may be noticeable in the stool.
Advise patients seek medical attention if tarry stools or other evidence of gastrointestinal bleeding is noticed.

Manufactured by

Strides Shasun Limited.

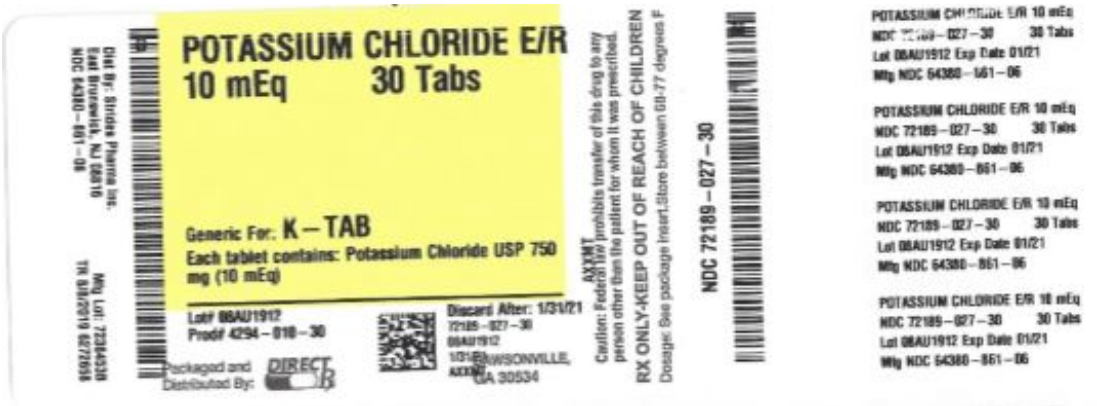
Bengaluru -562106, India.

Distributed by:

Strides Pharma Inc.,

East Brunswick, NJ 08816

Revised 08/2018



POTASSIUM CHLORIDE

potassium chloride tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72189-027(NDC:64380-861)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	750 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ETHYLCELLULOSE (10 MPA.S) (UNII: 3DYK7UYZ62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ETHYLCELLULOSE (100 MPA.S) (UNII: 47MLB0F1MV)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	yellow	**Score**	no score
Shape	ROUND (biconvex)	**Size**	12mm
Flavor		**Imprint Code**	P10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-027-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2019	
2	NDC:72189-027-04	4 in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210733	10/02/2019	

Labeler - Direct_Rx (079254320)

Registrant - Direct_Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Direct_Rx		079254320	repack(72189-027)

Revised: 1/2025 Direct_Rx