POTASSIUM CHLORIDE- potassium chloride capsule, extended release AvKARE

Potassium Chloride Extended-release Capsules, USP

Rx Only

DESCRIPTION:

Potassium Chloride Extended-release Capsules USP, 8 mEq and 10 mEq are oral dosage forms of

microencapsulated potassium chloride containing 600 mg and 750 mg of potassium chloride, USP

equivalent to 8 mEq and 10 mEq of potassium, respectively.

Dispersibility of potassium chloride (KCl) is accomplished by microencapsulation and a dispersing

agent. The resultant flow characteristics of the KCl microcapsules and the controlled release of K+

ions by the microcapsular membrane are intended to avoid the possibility that excessive amounts of KCl

can be localized at any point on the mucosa of the gastrointestinal tract.

Each crystal of KCl is microencapsulated by a process with an insoluble polymeric coating which

functions as a semi-permeable membrane; it allows for the controlled release of potassium and chloride

ions over an eight-to-ten-hour period. Fluids pass through the membrane and gradually dissolve the

potassium chloride within the micro-capsules. The resulting potassium chloride solution slowly

diffuses outward through the membrane. Potassium Chloride Extended-release Capsules, USP, 8 mEq

and 10 mEq are electrolyte replenishers.

The chemical name of the active ingredient is potassium chloride and the structural formula is KCl. It

has a molecular mass of 74.55. 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 inactive ingredients are, ethylcellulose, FD&C blue #1, FD&C red # 40, gelatin, sodium lauryl

sulfate, titanium oxide and triacetin.

CLINICAL PHARMACOLOGY:

12.1 Mechanis m 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

Each crystal of KCl is microencapsulated and allows for the controlled release of potassium and

chloride ions over an eight- to ten-hour period.

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.

INDICATIONS AND USAGE:

Potassium chloride extended-release capsules are indicated for the treatment and

prophylaxis of

hypokalemia in adults and children with or without metabolic alkalosis, in patients for whom dietary

management with potassium-rich foods or diuretic dose reduction is insufficient.

CONTRAINDICATIONS:

Potassium chloride extended-release capsules are contraindicated in patients on amiloride or

triamterene.

WARNINGS:

Solid oral dosage forms of potassium chloride can produce ulcerative and/or stenotic lesions of the

gastrointestinal tract, particularly if the drug is 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 capsules and consider possibility of ulceration, obstruction or

perforation.

Potassium chloride extended-release capsules should not be taken on an empty stomach because of its

potential for gastric irritation [see Dosage and Administration (2.1)].

PRECAUTIONS:

General The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. In interpreting the serum potassium level, the physician should bear in mind that acute alkalosis per se can produce hypokalemia in the absence of a deficit in total body potassium, while acute acidosis per se can increase the serum potassium concentration into the normal range even in the presence of a reduced total body potassium. The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis, requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the electrocardiogram, and the clinical status of the patient.

Information For Patients

Physicians should consider reminding the patient of the following: To take each dose with meals and with a full glass of water or other suitable liquid. To take each dose without crushing, chewing, or sucking the capsules. To take this medicine following the frequency and amount prescribed by the physician. This is especially important if the patient is also taking diuretics and/or digitalis preparations. To check with the physician if there is trouble swallowing capsules or if the capsules seem to stick in the throat.

To check with the physician at once if tarry stools or other evidence of gastrointestinal bleeding is noticed.

Laboratory Tests Regular serum potassium determinations are recommended, especially in patients with renal insufficiency or diabetic nephropathy. When blood is drawn for analysis of plasma potassium it is important to recognize that artifactual elevations can occur after improper venipuncture technique or as a result of in vitro hemolysis of the sample.

Drug Interactions Potassium-sparing diuretics, angiotensin converting enzyme inhibitors (see **WARNINGS**).

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

There are no human data related to use of potassium chloride extended-release capsules during

pregnancy and animal reproductive 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.

The normal potassium ion content of human milk is about 13 mEq per liter. Since oral potassium

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.

Clinical trial data from published literature have demonstrated the safety and effectiveness of potassium

chloride in children with diarrhea and malnutrition from birth to 18 years.

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.

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, and perforation.

Skin rash has been reported rarely.

To report SUSPECTED ADVERSE REACTIONS contact AvKARE, Inc. at 1-855-361-3993; email drugsafety@avkare.com; or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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.

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-waves, 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:

1. Monitor closely for arrhythmias and electrolyte changes.

2. Eliminate foods and medications containing potassium and 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 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.

DOSAGE AND ADMINISTRATION:

2.1 Adminis tration and Monitoring

If serum potassium concentration is <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

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

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 with meals and with a full glass of water or other liquid. Do not take on an empty stomach because

of the potential for gastric irritation [see Warnings and Precautions (5.1)].

Patients who have difficulty swallowing capsules may sprinkle the contents of the capsule onto a

spoonful of soft food. The soft food, such as applesauce or pudding, should be swallowed immediately

without chewing and followed with a glass of water or juice to ensure complete swallowing of the

microcapsules. Do not added to hot foods. Any microcapsule/food mixture should be used immediately

and not stored for future use.

2.2 Adult Dos ing

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 to 100 mEq per day.

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

2.3 Pediatric Dos ing

Pediatric patients aged birth to 16 years old: Dosage must be adjusted to the individual needs of each

patient. Do not exceed as a single dose 1 mEq/kg or 20 mEq, whichever is lower.

Treatment of hypokalemia: The recommended initial dose is 2 to 4 mEq/kg/day in divided doses. If

deficits are severe or ongoing losses are great, consider intravenous therapy.

Maintenance or Prophylaxis: Typical dose is 1 mEq/kg/day.

HOW SUPPLIED:

Potassium Chloride Extended-release Capsules, USP, 8 mEq are white opaque capsules, imprinted with Andrx logo on the cap and 559 on the body, each containing 600mg microencapsulated potassium chloride (equivalent to 8 mEq K) in bottles of 90 (NDC 42291-678-90).

Potassium Chloride Extended-release Capsules, USP, 10 mEq are dark blue opaque capsules, imprinted with Andrx logo on the cap and 560 on the body, each containing 750 mg microencapsulated potassium chloride (equivalent to 10 mEq K) in bottles of 90 (42291-679-90), bottles of 500 (42291-679-50).

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

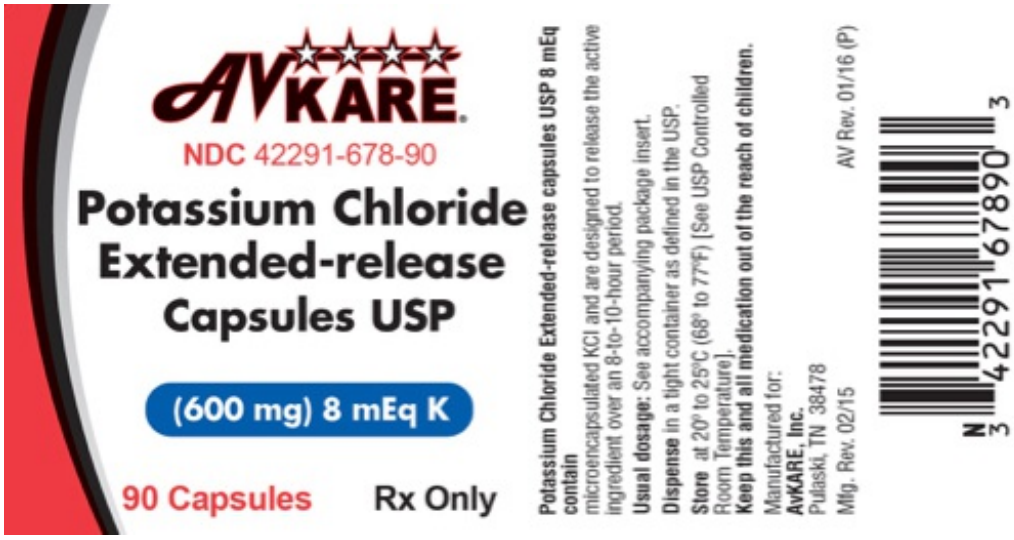
Dispense in a tight container as defined in the USP.

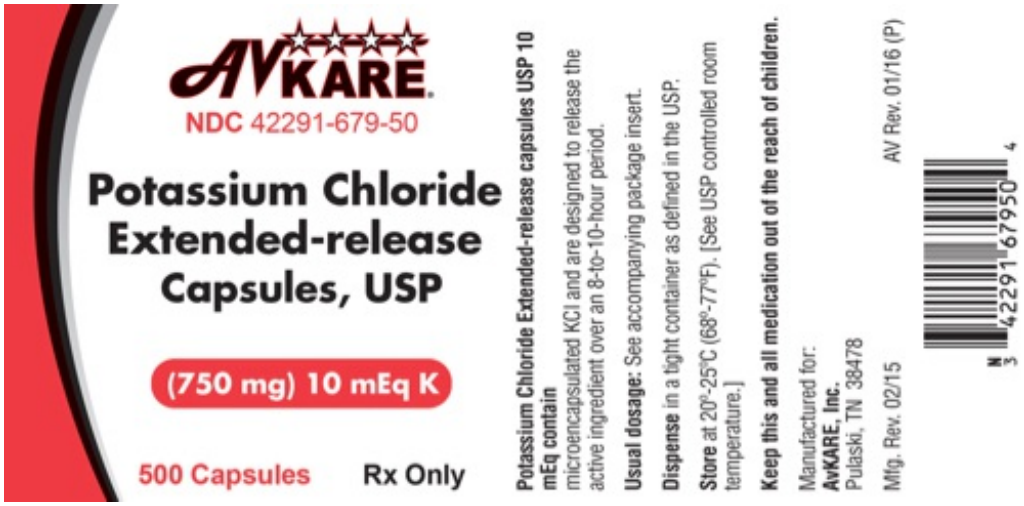
Manufactured for:
AvKARE, Inc.
Pulaski, TN 38478

Mfg. Rev. 02/15

AV Rev. 03/16 (P)

PRINCIPAL DISPLAY PANEL





POTASSIUM CHLORIDE

potassium chloride capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42291-678
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	600 mg

Inactive Ingredients

Ingredient Name	Strength
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
GELATIN (UNII: 2G86QN327L)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	white (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	23mm
Flavor		**Imprint Code**	Andrx;559
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:42291-678-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/05/2013	11/30/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077419	03/05/2013	11/30/2021

POTASSIUM CHLORIDE

potassium chloride capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42291-679
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
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	blue (Dark Blue Opaque)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	25mm
Flavor		**Imprint Code**	Andrx;560
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42291-679-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/05/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077419	03/05/2013	

Labeler - AvKARE (796560394)

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