

CYTRA-K CRYSTALS - potassium citrate and citric acid granule, for solution
Cypress Pharmaceutical, Inc.

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.

CYTRA-K
CRYSTALS
(Potassium Citrate and
Citric Acid for Oral Solution)

Rx Only

NDC 60258-005-01

DESCRIPTION

CYTRA-K CRYSTALS (potassium citrate and citric acid for oral solution) is a pleasant-tasting oral systemic alkalizer containing potassium citrate and citric acid in a sugar-free base.

Each packet of CYTRA-K CRYSTALS, when reconstituted, provides the following amounts of active ingredients :

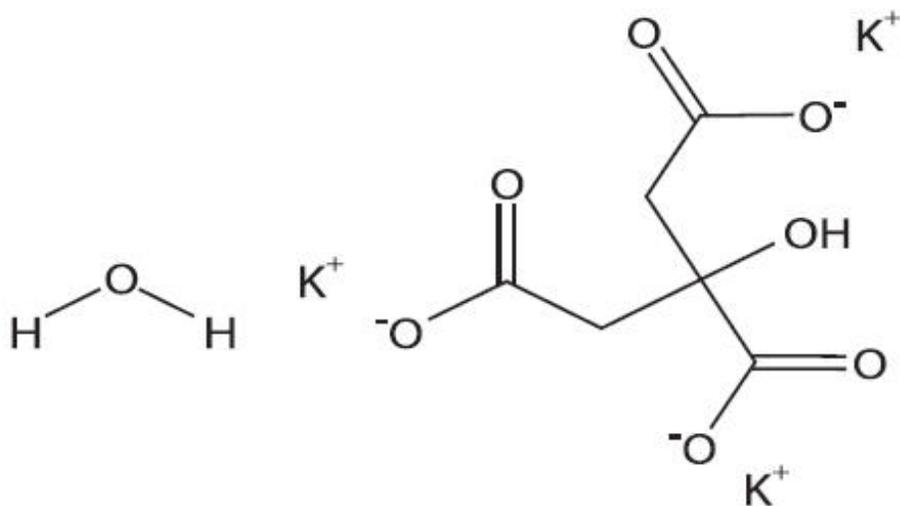
Potassium Citrate Monohydrate	3300 mg
Citric Acid Monohydrate	1002 mg

and provides 30 mEq potassium, equivalent to 30 mEq bicarbonate (HCO₃).

INACTIVE INGREDIENTS

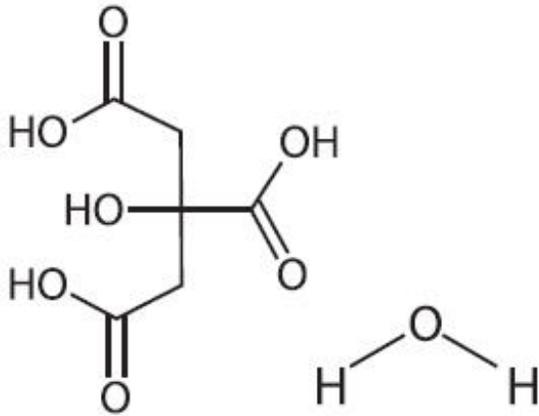
Sodium saccharin, fruit punch flavor, and FD&C Red Dye #3.

Potassium Citrate Monohydrate has the chemical name: 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, tripotassium salt, monohydrate. Its chemical structure is as follows:



$C_6H_5K_3O_7 \cdot H_2O$ M.W. 324.41

Citric Acid Monohydrate has the chemical name: 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate. Its chemical structure is as follows:



$C_6H_8O_7 \cdot H_2O$ M.W. 210.14

CLINICAL PHARMACOLOGY

Potassium citrate is absorbed and metabolized to potassium bicarbonate, thus acting as a systemic alkalinizer. The effects are essentially those of chlorides before absorption and those of bicarbonates subsequently. Oxidation is virtually complete so that less than 5% of the potassium citrate is excreted in the urine unchanged.

INDICATIONS AND USAGE

CYTRA-K CRYSTALS is an effective alkalinizing agent useful in those conditions where long-term maintenance of an alkaline urine is desirable, such as in patients with uric acid and cystine calculi of the urinary tract, especially when the administration of sodium salts is undesirable or contraindicated. In addition, it is a valuable adjuvant when administered with uricosuric agents in gout therapy, since urates tend to crystallize out of an acid urine. It is also effective in correcting the acidosis of certain renal tubular disorders where the administration of potassium citrate may be preferable. CYTRA-K CRYSTALS is highly concentrated, and when administered after meals and before bedtime, allows one to maintain an alkaline urinary pH around the clock, usually without the necessity of a 2 A.M. dose. CYTRA-K CRYSTALS alkalinizes the urine without producing a systemic alkalosis in recommended dosage. It is highly palatable, pleasant tasting, and tolerable, even when administered for long periods. Potassium citrate does not neutralize the gastric juice or disturb digestion.

CONTRAINDICATIONS

Severe renal impairment with oliguria or azotemia, untreated Addison's disease, adynamia episodica hereditaria, acute dehydration, heat cramps, anuria, severe myocardial damage, and hyperkalemia from any cause. Known hypersensitivity to any ingredients in this product.

WARNINGS AND PRECAUTIONS

There have been several reports, published and unpublished, concerning nonspecific small-bowel lesions consisting of stenosis, with or without ulceration, associated with the administration of enteric-coated thiazides with potassium salts. These lesions may occur with enteric-coated potassium tablets alone or when they are used with nonenteric-coated thiazides, or certain other oral diuretics. These small-bowel lesions have caused obstruction, hemorrhage, and perforation. Surgery was frequently required and deaths have occurred. Based on a large survey of physicians and hospitals, both United States and foreign, the incidence of these lesions is low, and a causal relationship in man has not been definitely established. Available information tends to implicate enteric-coated potassium salts, although lesions of this type also occur spontaneously. Therefore, coated potassium-containing formulations

should be administered only when indicated, and should be discontinued immediately if abdominal pain, distention, nausea, vomiting, or gastrointestinal bleeding occur. Large doses may cause hyperkalemia and alkalosis, especially in the presence of renal disease. Concurrent administration of potassium-containing medication, potassium-sparing diuretics, angiotensin-converting enzyme (ACE) inhibitors, or cardiac glycosides may lead to toxicity. Do not exceed recommended dosage. Discontinue use if adverse reactions occur.

Should be used with caution by patients with low urinary output unless under the supervision of a physician. As with all liquids containing a high concentration of potassium, patients should be directed to dilute adequately with water to minimize the possibility of gastrointestinal injury associated with the oral ingestion of concentrated potassium salt preparations; and preferably, to take each dose after meals to avoid saline laxative effect.

ADVERSE REACTIONS

CYTRA-K CRYSTALS is generally well tolerated without any unpleasant side effects when given in recommended doses to patients with normal renal function and urinary output. However, as with any alkalinizing agent, caution must be used in certain patients with abnormal renal mechanisms to avoid development of hyperkalemia or alkalosis. Potassium intoxication causes listlessness, weakness, mental confusion, tingling of extremities, and other symptoms associated with a high concentration of potassium in the serum. Periodic determinations of serum electrolytes should be carried out in those patients with renal disease in order to avoid these complications. Hyperkalemia may exhibit the following electrocardiographic abnormalities: Disappearance of the P wave, widening and slurring of QRS complex, changes of the S-T segment, tall peaked T waves, etc.

OVERDOSAGE

The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired, hyperkalemia can result (see Contraindications and Warnings). Hyperkalemia, when detected, must be treated immediately because lethal levels can be reached in a few hours.

Treatment

Should hyperkalemia occur, treatment measures include the following:

(1) Elimination of foods or medications containing potassium. (2) The intravenous administration of 300 to 500 mL/hr of dextrose solution (10 to 25%), containing 10 units of insulin/20 gm dextrose. (3) The 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 plasma potassium concentration can produce digitalis toxicity.

DOSAGE AND ADMINISTRATION

CYTRA-K CRYSTALS should be taken mixed in cool water or juice according to directions, followed by additional water or juice, if desired. Proper dilution may help prevent gastrointestinal injury associated with the oral ingestion of concentrated potassium salt preparations.

Usual Adult Dose

CYTRA-K CRYSTALS - Contents of 1 packet reconstituted with at least 6 ounces of cool water or juice, after meals and at bedtime, or as directed by physician.

Usual Pediatric Dose

CYTRA-K CRYSTALS is not recommended for pediatric use.

Usual Dosage Range

Contents of 1 packet CYTRA-K CRYSTALS, reconstituted as directed and taken four times a day, will usually maintain a urinary pH of 6.5-7.4. To check urinary pH, HYDRION Paper (pH 6.0-8.0) or NITRAZINE Paper (pH 4.5-7.5) are available and easy to use.

HOW SUPPLIED

CYTRA-K CRYSTALS - 100 Packets/box (NDC 60258-005-01).

STORAGE

Store at controlled room temperature, 15°-30°C (59°-86°F). Protect from excessive heat or freezing.

KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSAGE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

Call your doctor for medical advice about side effects. You may report side effects to Cypress Pharmaceutical, Inc. at 1-800-793-2145 or FDA at 1-800-FDA-1088.

Rx Only

Manufactured for: Cypress Pharmaceutical, Inc., Morristown, NJ 07960

I185

PN 0654C

Rev. 09/16

PRINCIPAL DISPLAY PANEL - 4.32 g Packet Box

NDC 60258-005-01

CYTRA-K CRYSTALS

(POTASSIUM CITRATE AND CITRIC ACID FOR ORAL SOLUTION)

FRUIT-FLAVORED • SUGAR-FREE

CYPRESS

PHARMACEUTICAL, INC.

100 Packets - Net weight per packet: 4.32 g

NDC 60258-005-01

CYTRA-K CRYSTALS

(POTASSIUM CITRATE AND CITRIC ACID FOR ORAL SOLUTION)

FRUIT-FLAVORED • SUGAR-FREE



100 Packets - Net weight per packet: 4.32 g

DESCRIPTION: CYTRA-K CRYSTALS (potassium citrate and citric acid for oral solution) is a pleasant-tasting oral systemic alkalizer containing potassium citrate and citric acid in a sugar-free base.

Each packet, when reconstituted, provides the following amounts of active ingredients:

Potassium Citrate Monohydrate 3300 mg
Citric Acid Monohydrate 1002 mg
and provides 30 mEq Potassium, equivalent to 30 mEq Bicarbonate (HCO₃)

INACTIVE INGREDIENTS: Sodium saccharin, fruit punch flavor, and FD&C Red Dye #3.

100 Packets - Net weight per packet: 4.32 g



FRUIT-FLAVORED • SUGAR-FREE

CYTRA-K CRYSTALS

(POTASSIUM CITRATE AND CITRIC ACID FOR ORAL SOLUTION)

NDC 60258-005-01

Please see full prescribing information inside this carton for complete product information.
 Call your doctor for medical advice about side effects. You may report side effects to Cypress Pharmaceutical, Inc. at 1-800-793-2145 or FDA at 1-800-FDA-1088.

Rx Only

Manufactured for: Cypress Pharmaceutical, Inc., Morristown, NJ 07960
 B0011 PN 0653B Rev. 09/16

Lot No.:
 Exp. Date:

Non-Varnish Area

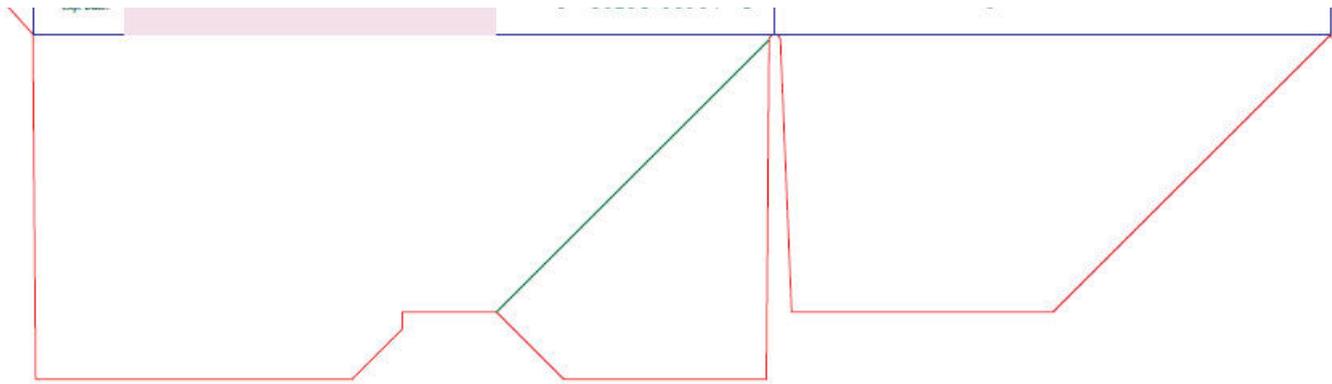


Directions: Mix contents of 1 packet with 6 ounces of cool water or juice. Stir well and take promptly. Take after meals and at bedtime, or as directed by physician.

NOTE: Proper dilution may help prevent gastrointestinal injury associated with the oral ingestion of concentrated potassium salt preparations.

KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSAGE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

STORAGE: Store at controlled room temperature, 15°-30°C (59°-86°F). Protect from excessive heat or freezing.



CYTRA-K CRYSTALS

potassium citrate and citric acid granule, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60258-005
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Potassium Citrate (UNII: EE90ONI6FF) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Potassium Citrate	3.3 g
Citric Acid Monohydrate (UNII: 2968PHW8QP) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	1.002 g

Inactive Ingredients

Ingredient Name	Strength
Saccharin Sodium Anhydrous (UNII: I4807BK602)	33 mg

Product Characteristics

Color	red (FD&C Red Dye #3)	Score	
Shape		Size	
Flavor	FRUIT PUNCH	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60258-005-01	100 in 1 BOX; Type 0: Not a Combination Product	05/01/2003	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2003	

Labeler - Cypress Pharmaceutical, Inc. (790248942)

Registrant - Cypress Pharmaceutical, Inc. (790248942)

Establishment

Name	Address	ID/FEI	Business Operations
Tower Laboratories Ltd		001587203	manufacture(60258-005)

Revised: 9/2016

Cypress Pharmaceutical, Inc.