K PHOS ORIGINAL- potassium phosphate, monobasic tablet, soluble
Carilion Materials Management

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.

K-PHOS® ORIGINAL Potassium Acid Phosphate

DESCRIPTION

Each tablet contains potassium acid phosphate 500 mg. Each tablet yields approximately 114 mg of phosphorus and 144 mg of potassium or 3.7 mEq.

Inactive ingredients: Magnesium stearate, microcrystalline cellulose, silicon dioxide, starch, stearic acid.

ACTIONS

K-PHOS® ORIGINAL is a highly effective sodium-free urinary acidifier.

INDICATONS AND USAGE

For use in patients with elevated urinary pH. K-PHOS® ORIGINAL helps keep calcium soluble and reduces odor and rash caused by ammoniacal urine. Also, by acidifying the urine, it increases the antibacterial activity of methenamine mandelate and methenamine hippurate.

CONTRAINDICATIONS

This product is contraindicated in patients with infected phosphate stones; in patients with severely impaired renal function (less than 30% of normal) and in the presence of hyperphosphatemia and hyperkalemia.

PRECAUTIONS

General

This product contains potassium and should be used with caution if regulation of this element is desired. Occasionally, some individuals may experience a mild laxative effect during the first few days of phosphate therapy. If laxation persists to an unpleasant degree, reduce the daily dosage until this effect subsides or, if necessary, discontinue the use of this product.

Caution should be exercised when prescribing this product in the following conditions: Cardiac disease (particularly in digitalized patients); severe adrenal insufficiency (Addison's disease); acute dehydration; severe renal insufficiency or chronic renal disease; extensive tissue breakdown (such as severe burns); myotonia congenita; hypoparathyroidism; and acute pancreatitis. Rickets may benefit from phosphate therapy, but caution should be exercised. High serum phosphate levels may increase the incidence of extra-skeletal calcification.

Information for Patients

Patients with kidney stones may pass old stones when phosphate therapy is started and should be warned of this possibility. Patients should be advised to avoid the use of antacids containing aluminum, calcium, or magnesium, which may prevent the absorption of phosphate. To assure against gastrointestinal injury associated with oral ingestion of concentrated potassium salt preparations, patients should be instructed to dissolve tablets completely in an appropriate amount of water before taking.

Laboratory Tests

Careful monitoring of renal function and serum calcium, phosphorus and potassium may be required at periodic intervals during potassium phosphate therapy. Other tests may be warranted in some patients, depending on conditions.

Drug Interactions

The use of antacids containing magnesium, calcium, or aluminum in conjunction with phosphate preparations may bind the phosphate and prevent its absorption. Potassium-containing medications or potassium-sparing diuretics may cause hyperkalemia when used concurrently with potassium salts. Patients should have serum potassium level determinations at periodic intervals. Concurrent use of salicylates may lead to increased serum salicylate levels since excretion of salicylates is reduced in acidified urine. Serum salicylate levels should be closely monitored to avoid toxicity.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term or reproduction studies in animals or humans have been performed with K-PHOS® ORIGINAL to evaluate its carcinogenic, mutagenic, or impairment of fertility potential.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with K-PHOS® ORIGINAL. It is also not known whether this product can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. This product should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

ADVERSE REACTIONS

Gastrointestinal upset (diarrhea, nausea, stomach pain, and vomiting) may occur with the use of potassium phosphate. Also, bone and joint pain (possible phosphate-induced osteomalacia) could occur. The following adverse effects may be observed with potassium administration: irregular heartbeat; dizziness; mental confusion; weakness or heaviness of legs; unusual tiredness; muscle cramps; numbness, tingling, pain, or weakness in hands or feet; numbness or tingling around lips; shortness of breath or troubled breathing.

DOSAGE AND ADMINISTRATION

Two tablets dissolved in 6-8 oz. of water 4 times daily with meals and at bedtime. For best results, let the tablets soak in water for 2 to 5 minutes, or more if necessary, and stir. If any tablet particles remain undissolved, they may be crushed and stirred vigorously to speed dissolution.

HOW SUPPLIED

NDC:68151-2193-0 in a PACKAGE of 1 TABLET, SOLUBLES

STORAGE

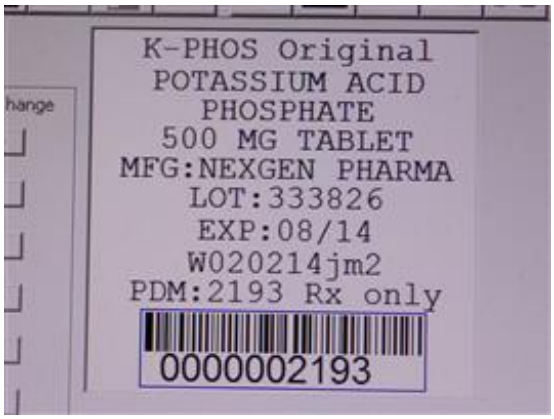
Keep tightly closed. Store at controlled room temperature, 20°-25°C (68°-77°F).

Dispense in tight, light-resistant containers with child-resistant closures.

BEACH PHARMACEUTICALS, Div. of Beach Products, Inc., Tampa, FL 33611

Rev: 07/09B

Potassium Acid Phosphate 500 mg tabs



K PHOS ORIGINAL

potassium phosphate, monobasic tablet, soluble

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68151-2193(NDC:0486-1111)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Potassium Phosphate, Monobasic (UNII: 4J9FJ0HL51) (Phosphate Ion - UNII:NK08V8K8HR, Potassium Cation - UNII:295O53K152)	Potassium Phosphate, Monobasic	500 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Starch, Corn (UNII: O8232NY3SJ)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Magnesium Stearate (UNII: 70097M6I30)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	BEACH;1111
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68151-2193-0	1 in 1 PACKAGE; Type 0: Not a Combination Product	03/29/1977	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		03/29/1977	

Labeler - Carilion Materials Management (079239644)

Registrant - Carilion Materials Management (079239644)

Establishment

Name	Address	ID/FEI	Business Operations
Carilion Materials Management		079239644	REPACK(68151-2193)

Revised: 9/2014 Carilion Materials Management