K-PHOS NO. 2- potassium phosphate, monobasic and sodium phosphate, monobasic, anhydrous tablet, coated
Beach Products, 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.

K-PHOS® No. 2

Urinary Acidifier

Rx ONLY

DESCRIPTION

Each tablet contains potassium acid phosphate 305 mg and sodium acid phosphate, anhydrous, 700 mg. Each tablet yields approximately 250 mg of phosphorus, 88 mg of potassium or 2.3 mEq and 134 mg of sodium or 5.8 mEq.

Inactive ingredients: Lactose, magnesium stearate, microcrystalline cellulose, povidone, purified water, sodium starch glycolate, stearic acid, talc, brown coating (FD&C Blue No. 2, FD&C Red No. 40, FD&C Yellow No. 6, hypromellose, polyethylene glycol, polydextrose, titanium dioxide, triacetin).

CLINICAL PHARMACOLOGY

Phosphorus has a number of important functions in the biochemistry of the body. The bulk of the body's phosphorus is located in the bones, where it plays a key role in osteoblastic and osteoclastic activities. Enzymatically catalyzed phosphate-transfer reactions are numerous and vital in the metabolism of carbohydrate, lipid and protein, and a proper concentration of the anion is of primary importance in assuring an orderly biochemical sequence. In addition, phosphorus plays an important role in modifying steady-state tissue concentrations of calcium. Phosphate ions are important buffers of the intracellular fluid, and also play a primary role in the renal excretion of hydrogen ion.

Oral administration of inorganic phosphates increases serum phosphate levels. Phosphates lower urinary calcium levels in idiopathic hypercalciuria.

In general, in adults, about two thirds of the ingested phosphate is absorbed from the bowel, most of which is rapidly excreted into the urine.

INDICATONS AND USAGE

K-PHOS® No. 2 is a highly effective urinary acidifier for use in patients with elevated urinary pH. This product 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.

PRECAUTIONS

General

This product contains potassium and sodium and should be used with caution if regulation of these elements 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.

Use of this medication should be carefully considered when the following medical problems exist: Cardiac disease (particularly in digitalized patients), Addison's disease, acute dehydration, extensive tissue breakdown, myotonia congenita, cardiac failure, cirrhosis of the liver or severe hepatic disease, peripheral and pulmonary edema, hypernatremia, hypertension, toxemia of pregnancy, hypoparathyroidism, and acute pancreatitis. Rickets may benefit from phosphate therapy, but caution should be observed. High serum phosphate levels increase the risk of extraskeletal 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, magnesium, or calcium which may prevent the absorption of phosphate.

Laboratory Tests

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

Drug Interactions

The use of antacids containing magnesium, aluminum, or calcium in conjunction with phosphate preparations may bind the phosphate and prevent its absorption. Concurrent use of antihypertensives, especially diazoxide, guanethidine, hydralazine, methyldopa, or rauwolfia alkaloid; or corticosteroids, especially mineralocorticoids or corticotropin, with sodium phosphate may result in hypernatremia. Potassium-containing medications or potassium-sparing diuretics may cause hyperkalemia when used wi t h potassium phosphate. Patients should have serum potassium level determinations at periodic intervals. Plasma levels of salicylates may be increased since salicylate excretion is decreased in acidified urine. Administration of monobasic phosphates to patients stabilized on salicylates may lead to toxic salicylate levels.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term or reproduction studies in animals or humans have been performed with K-PHOS® No. 2 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® No. 2. 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 phosphate therapy. Also, bone and joint pain (possible phosphate-induced osteomalacia) could occur. The following adverse effects may be observed (primarily from sodium or potassium): headaches; dizziness; mental confusion; seizures; weakness or heaviness of legs; unusual tiredness or weakness; muscle cramps; numbness, tingling, pain, or weakness of hands or feet; numbness or tingling around lips; fast or irregular heartbeat; shortness of breath or troubled breathing; swelling of feet or lower legs; unusual weight gain; low urine output; unusual thirst.

DOSAGE AND ADMINISTRATION

One tablet four times daily with a full glass of water. When the urine is difficult to acidify, administer one tablet every two hours not to exceed 8 tablets in a 24-hour period.

HOW SUPPLIED

K-PHOS® No.2 is supplied as a brown, scored, capsule-shaped tablet with the name BEACH and the number 1134 imprinted on each tablet. Bottles of 100 (NDC 0486- 1134-01).

STORAGE

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

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

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

Rev: 07/09B

PRINCIPAL DISPLAY PANEL - 250 mg Tablet Bottle Label

NDC 0486-1134-01

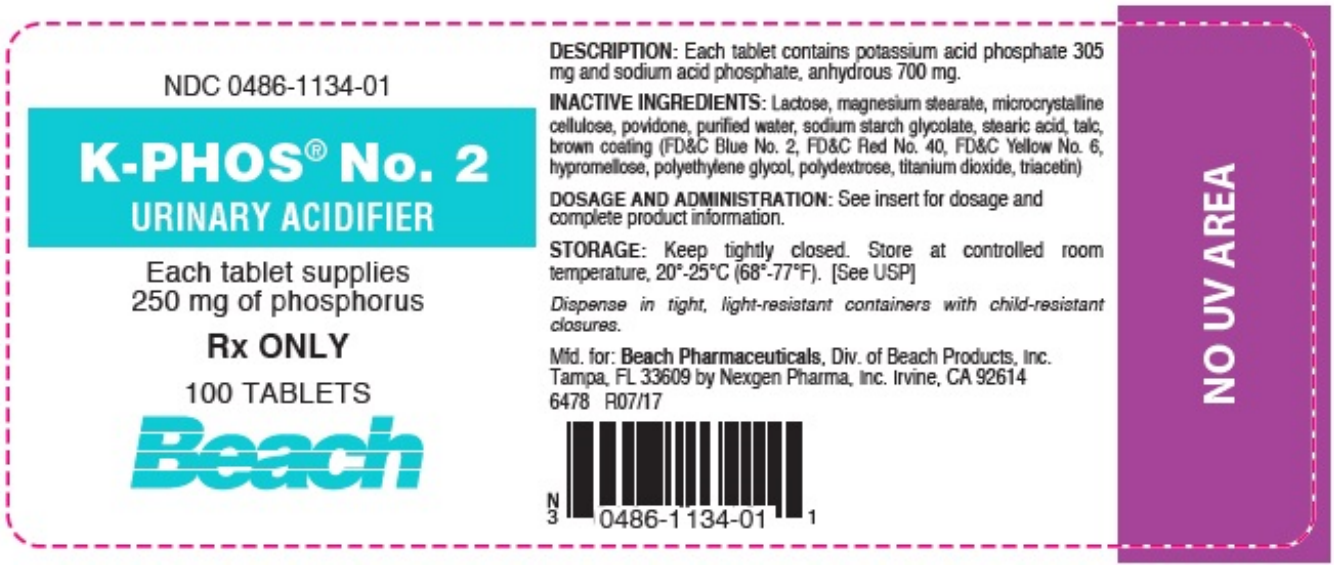
K-PHOS ® No. 2
URINARY ACIDIFIER

Each tablet supplies
250 mg of phosphorus

Rx ONLY

100 TABLETS

Beach



K-PHOS NO. 2

potassium phosphate, monobasic and sodium phosphate, monobasic, anhydrous tablet, coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0486-1134
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	305 mg
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS	700 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
WATER O-18 (UNII: 7QV8F8BYNJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	

Product Characteristics			
Color	brown	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	BEACH;11;34
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0486-1134-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/09/1978	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/09/1978	

Labeler - Beach Products, Inc. (032763633)

Establishment

Name	Address	ID/FEI	Business Operations
Nexgen Pharma		160356114	manufacture(0486-1134)

Revised: 8/2019 Beach Products, Inc.