K PHOS NEUTRAL- sodium phosphate, dibasic, anhydrous, potassium phosphate, monobasic, and sodium phosphate, monobasic, monohydrate 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® NEUTRAL

Phosphorus Supplement

Rx ONLY

DESCRIPTION

Each tablet contains 852 mg dibasic sodium phosphate anhydrous, 155 mg monobasic potassium phosphate, and the equivalent of 130 mg monobasic sodium phosphate monohydrate. Each tablet yields approximately 250 mg of phosphorus, 298 mg of sodium (13.0 mEq) and 45 mg of potassium (1.1 mEq). The components of K-PHOS® NEUTRAL have the following chemical names and molecular formulae:

Dibasic Sodium Phosphate, Anhydrous
Molecular Formula: Na_2HPO_4, Molecular Weight: 141.96.

Monobasic Potassium Phosphate
Molecular Formula: KH_2PO_4, Molecular Weight: 136.09.

Monobasic Sodium Phosphate, Monohydrate
Molecular Formula:$NaH_2PO_4.H_2O$, Molecular Weight: 137.98.

Inactive Ingredients: Lactose monohydrate, povidone, white coating (hydroxypropyl methylcellulose, titanium dioxide, maltodextrin, triacetin, glycerol triacetate, polyethylene glycol, sodium citrate, and stearic acid), sodium starch glycolate, and magnesium stearate.

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.

INDICATIONS AND USAGE

K-PHOS® NEUTRAL increases urinary phosphate and pyrophosphate. As a phosphorus supplement, each tablet supplies 25% of the U.S. Recommended Daily Allowance (U.S.RDA) of phosphorus for adul t s and children over 4 years of age.

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.

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; renal function impairment or chronic renal disease; extensive tissue breakdown (such as severe burns); myotonia congenita; cardiac failure; cirrhosis of the liver or severe hepatic disease; peripheral or pulmonary edema; hypernatremia; hypertension; toxemia of pregnancy; 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, 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. Calciumcontaining preparations and/or Vitamin D may antagonize the effects of phosphates in the treatment of hypercalcemia. Potassium-containing medications or potassium-sparingdiuretics may cause hyperkalemia. Patients should have serum potassium level determinations at periodic intervals.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term or reproduction studies in animals or humans have been performed with K-PHOS ® NEUTRAL 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® NEUTRAL. 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.

Pediatric Use

See DOSAGE AND ADMINISTRATION

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

K-PHOS® NEUTRAL tablets should be taken with a full glass of water, with meals and at bedtime. Adults: One or two tablets four times daily; Pediatric Patients over 4 years of age: One tablet four times daily. For Pediatric Patients under 4 years of age, use only as directed by a physician.

HOW SUPPLIED

White, film coated, capsule-shaped tablet with the name BEACH and the number 1125 imprinted on each tablet. Bottles of 100 (NDC 0486-1125-01) and bottles of 500 (NDC 0486-1125-05) tablets.

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: 06/05B

PRINCIPAL DISPLAY PANEL - 250 mg Tablet Bottle Label

NDC 0486-1125-01

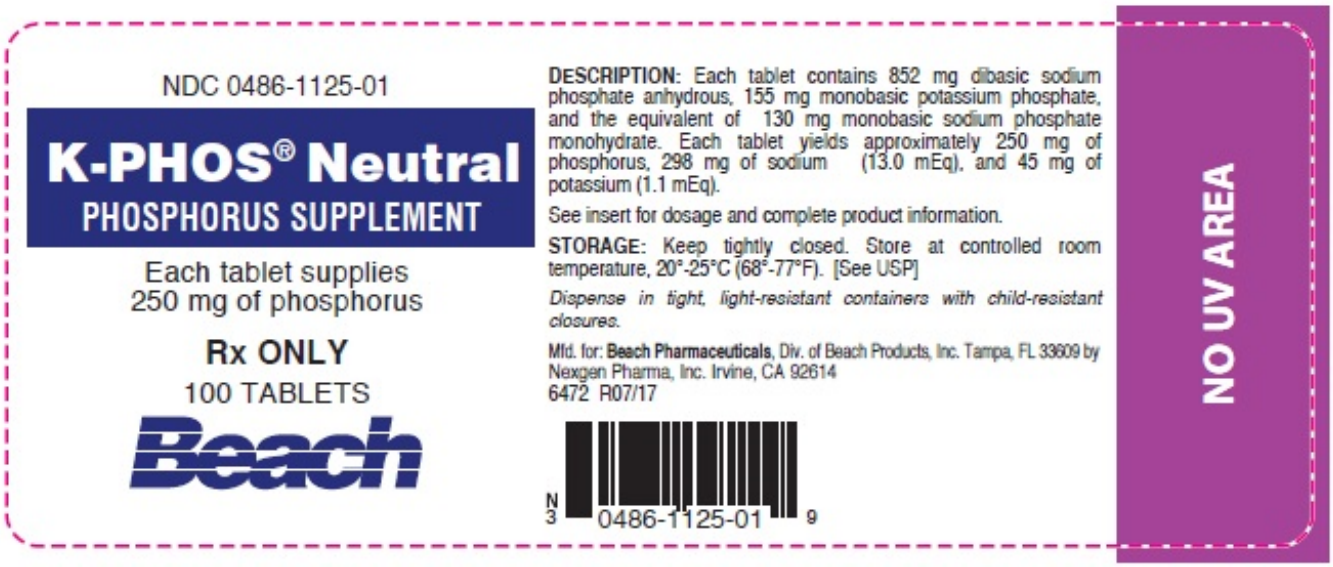
K-PHOS ® Neutral
PHOSPHORUS SUPPLEMENT

Each tablet supplies
250 mg of phosphorus

Rx ONLY

100 TABLETS

Beach



K PHOS NEUTRAL

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

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0486-1125
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, DIBASIC, ANHYDROUS	852 mg
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51) (PHOSPHATE ION - UNII:NK08V8K8HR, POTASSIUM CATION - UNII:295O53K152)	POTASSIUM PHOSPHATE, MONOBASIC	155 mg
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	130 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POVIDONE K29/32 (UNII: 390RMW2PEQ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
TRIACETIN (UNII: XHX3C3X673)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	Beach;11;25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0486-1125-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/11/1977	
2	NDC:0486-1125-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/11/1977	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/11/1977	

Labeler - Beach Products, Inc. (032763633)

Establishment

Name	Address	ID/FEI	Business Operations
Nexgen Pharma		160356114	manufacture(0486-1125)

Revised: 8/2019 Beach Products, Inc.