DIBASIC SODIUM PHOSPHATE, MONOBASIC POTASSIUM PHOSPHATE AND MONOBASIC SODIUM PHOSPHATE- dibasic sodium phosphate, monobasic potassium phosphate and monobasic sodium phosphate tablet
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.

PHOSPHA 250™ NEUTRAL Supplies 250 mg of phosphorus per tablet

DESCRIPTION

Each tablet contains 852 mg dibasic sodium phosphate anhydrous, 155 mg monobasic potassium phosphate, and 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).

OTHER INGREDIENTS

Purified Water, Lactose Monohydrate, Sodium Starch Glycolate, Polyvinyl Pyrrolidone, Magnesium Stearate, Hydroxypropyl methylcellulose, Polyethylene Glycol 400, Titanium dioxide.

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. ln 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 the 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 in absorbed from the bowel, most of which is rapidly excreted into the urine.

INDICATIONS AND USAGE

PHOSPHA 250 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 adults and children over 4 years of age. TM

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 dose until this effect subsides or, if necessary, discontinue the use of the 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 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. Calcium-containing preparations and/or Vitamin D may antagonize the effects of phosphates in the treatment of hypercalcemia. Potassium-containing medication or potassium-sparing diuretics 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 PHOSPHA 250 NEUTRAL to evaluate its carcinogenic, mutagenic, or impairment of fertility potential. TM

Pregnancy:

Teratogenic Effects. Pregnancy Class C.

Animal reproduction studies have not been conducted with PHOSPHA 250 NEUTRAL. It is also not known whether this product can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. TM

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

PHOSPHA 250 NEUTRAL tablets should be taken with a full glass of water, with meals and at bedtime.
TM

One or two tablets, four times daily; **Adults:**

One tablet four times daily. **Pediatric patients over 4 years of age:**

Use only as directed by physician. **Pediatric Patients under 4 years of age:**

HOW SUPPLIED

NDC:68151-2195-0 in a PACKAGE of 1 TABLETS

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.

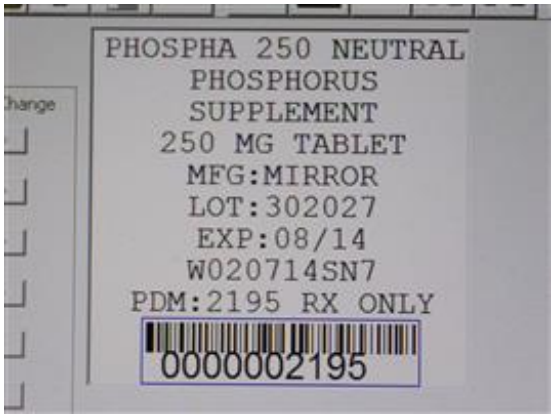
IDENTITY: Phospha 250 Neutral TM

is an orally administered medical food for use only under medical supervision for the dietary management of hypophosphatemia.

Manufactured for: 3 Pearl Court Allendale, NJ 07 401
Rising Pharmaceuticals, Inc.

Manufactured by: Fairfield, NJ 07004
Mirror Pharmaceuticals LLC.

Phospha Neutral 250 mg tablet



DIBASIC SODIUM PHOSPHATE, MONOBASIC POTASSIUM PHOSPHATE AND MONOBASIC SODIUM PHOSPHATE

dibasic sodium phosphate, monobasic potassium phosphate and monobasic sodium phosphate tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68151-2195(NDC:64980-104)
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 PHOSPHATE, DIBASIC, ANHYDROUS	852 mg
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51) (PHOSPHATE ION - UNII:NK08V8K8HR)	POTASSIUM PHOSPHATE, MONOBASIC	155 mg
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	130 mg

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE K30 (UNII: U725QWY32X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (15000 MPA.S) (UNII: 288VBX44JC)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE	**Score**	2 pieces
Shape	CAPSULE	**Size**	9mm
Flavor		**Imprint Code**	RIS;104
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68151-2195-0	1 in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		06/28/2012	

Labeler - Carilion Materials Management (079239644)

Registrant - Carilion Materials Management (079239644)

Establishment

Name	Address	ID/FEI	Business Operations
Carilion Materials Management		079239644	REPACK(68151-2195)

Revised: 6/2012 Carilion Materials Management