PHOSPHOROUS DIETARY SUPPLEMENT- phosphorous tablet
BROOKFIELD PHARMACEUTICALS, LLC

Phosphorous Tablets

Phosphorus Dietary Supplement -supplying 250 mg per tablet
71351-011-01

DESCRIPTION

Phosphorous Tablets is a prescription phosphorus dietary supplement - supplying 250 mg phosphorus per tablet for use in the dietary management of hypophosphatemia and should be administered under the supervision of a licensed medical practitioner.

Supplement Facts

Serving Size: 1 tablet
Servings per Container: 100

	Amount per Serving	%Daily Value
Sodium	298 mg	13%
Potassium	45 mg	1%
Phosphorus	250 mg	20%
(from a minimum of: 852 mg of Dibasic Sodium Phosphate, 155 mg of Monobasic Potassium Phosphate, 130 mg of Monobasic Sodium Phosphate)		

Other Ingredients

Microcrystalline Cellulose, Povidone, Coating (Hypromellose, Titanium Dioxide and Polyethylene Glycol), Croscarmellose Sodium, Stearic Acid, Magnesium Stearate, Silicon Dioxide.

INDICATIONS AND USAGE

As a phosphorus supplement, each tablet supplies 20% of the U.S. Recommended Daily Allowance (U.S. RDA) of phosphorus for adults and
children over 4 years of age. Phosphorous Tablets increases urinary phosphate and pyrophosphate.

Contraindications

This product is contradicted in patients with infected phosphate stones in the urinary tract, 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 clinical management of these elements is desired. Some individuals may experience a mild laxative effect during the first few days of phosphate supplementation; lower 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 patients receiving digitalis); severe adrenal insufficiency (Addison's disease); acute dehydration; severe renal insufficiency; renal function impairment or chronic renal disease; extensive tissue breakdown (such as with 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. High serum phosphate levels may increase the incidence of extraskeletal calcification.

Information for Patients
Patients with kidney stones may pass old stones when phosphate supplementation is started and should be warned of this possibility. Patients should be advised to avoid the use of antacids containing aluminum, magnesium, or calcium because they 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 supplementation. 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 antihypertensive drugs or corticosteroids 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 Phosphorous Tablets to evaluate its carcinogenic, mutagenic, or impairment of fertility potential.

Pregnancy and Lactation
Animal reproduction studies have not been conducted with Phosphorous Tablets. 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.

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

Pediatric Use: See DIRECTIONS FOR USE.

SIDE EFFECTS

Gastrointestinal upset (diarrhea, nausea, stomach pain, or vomiting) may occur with phosphate supplementation. Bone and joint pain and possibly osteomalacia could occur.

Adverse effects due to sodium or potassium may be observed: headache; dizziness; mental confusion; seizures; weakness or heaviness of legs; unusual tiredness or

weakness; 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.

DIRECTIONS FOR USE

Phosphorous Supplement Tablets should be taken with a full glass of water, with food, and at bedtime.

Adults: One tablet four times to eight times daily.
Pediatric patients over 4 years of age: One tablet four times daily.
Pediatric Patients under 4 years of age: Use only as directed by a licensed physician.

STORAGE

Store at 20° to 25°C (68° to 77°F). Excursions permitted to 15° to 30°C (59° to 86°F). Protect from light and moisture. Dispense in a tight, light-resistant container.

HOW SUPPLIED

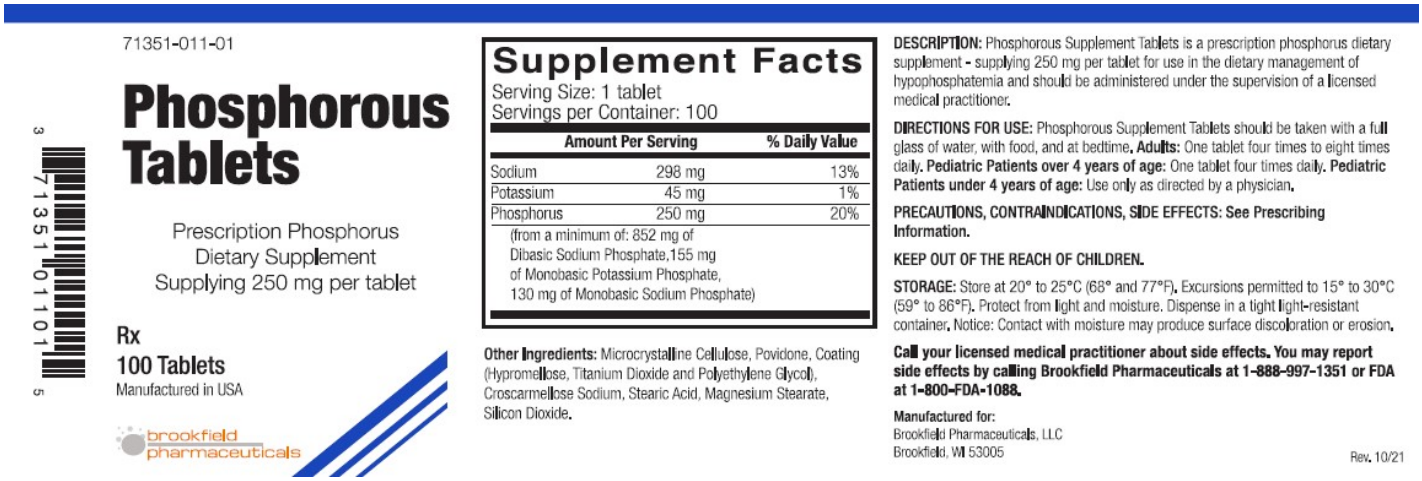
Phosphorous Tablets is supplied as white tablet dispensed in bottles of 100 tablets.
71351-011-01

KEEP THIS OUT OF REACH OF CHILDREN
Call your licensed medical practitioner about side effects. You may report side effects by calling Brookfield Pharmaceuticals at 1-888-997-1351 or FDA at 1-800-FDA-1088.

Manufactured for:
Brookfield Pharmaceuticals, LLC
Brookfield, WI 53005

MADE IN USA

Rev. 10/21



PHOSPHOROUS DIETARY SUPPLEMENT
phosphorous tablet

Product Information			
Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:71351-011
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM	852 mg
MONOBASIC POTASSIUM PHOSPHATE (UNII: 4J9FJ0HL51) (PHOSPHATE ION - UNII:NK08V8K8HR)	MONOBASIC POTASSIUM PHOSPHATE	155 mg
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM	130 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NHRIC:71351-011-01	100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		10/13/2023	

Supplement Facts

Serving Size : **Serving per Container :**

Amount Per Serving	% Daily Value
color	
shape	
size (solid drugs) 17 mm	

scoring	1

Labeler - BROOKFIELD PHARMACEUTICALS, LLC (080592685)

Revised: 10/2023 BROOKFIELD PHARMACEUTICALS, LLC