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

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**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 rolein 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 excretionof 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$^{TM}$ 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.

## 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:** 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 preventits 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$^{TM}$ NEUTRAL to evaluate its carcinogenic, mutagenic, or impairment of fertility potential.

**Pregnancy:**

Teratogenic Effects. Pregnancy Class C. Animal reproduction studies have not been conducted with PHOSPHA 250 TM 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 thisproduct 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.

**To report SUSPECTED ADVERSE REACTIONS, contact Ingenus Pharmaceuticals, LLC at 1-877-748-1970 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch**

## DOSAGE AND ADMINISTRATION

PHOSPHA 250™ 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.

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

## HOW SUPPLIED

White, film-coated, capsule-shaped tablet, debossed with RIS 104 on each tablet.

NDC #64980-104-01
Bottles of 100 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 250TM Neutral

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

**Manufactured by:**
Ingenus Pharmaceuticals NJ, LLC.
Fairfield, NJ 07004
**Distributed by:**
Rising Pharmaceuticals, Inc.
Saddle Brook, NJ 07663

**Rx only**

550301 Rev: 08/18

## PACKAGE LABEL.PRINCIPAL DISPLAY - 250 mg

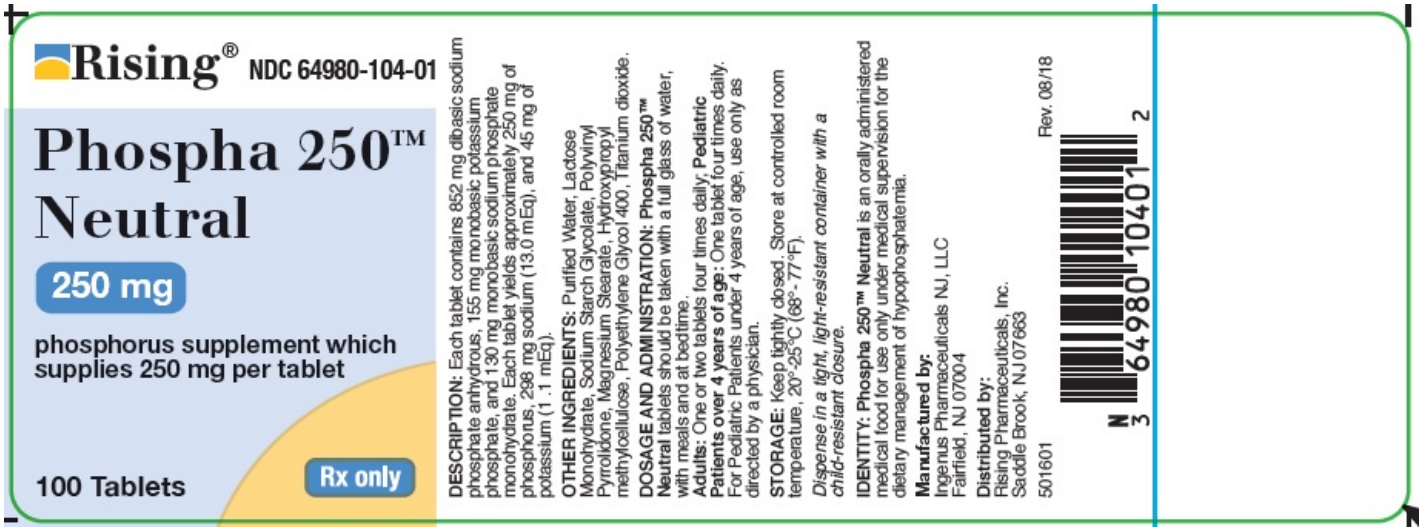
**Rising® NDC 64980-104-01**

**Phospha 250™**
**Neutral**

**phosphourus supplement which**
**supplies 250 mg per tablet**

**100 Tablets**

**Rx Only**




# 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: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:64980-104-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 06/28/2012 | |

## Marketing Information

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

## Labeler - Rising Pharmaceuticals, Inc. (041241766)

## Registrant - Ingenus Pharmaceuticals NJ, LLC (964680206)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Ingenus Pharmaceuticals NJ, LLC | | 964680206 | MANUFACTURE(64980-104) |

Revised: 10/2018 Rising Pharmaceuticals, Inc.