Customer: Mirror Pharmaceuticals

Product Name: Phospha 250 Neutral Topsert

Folded size: 1.2500” x 1.2500”

Flat sheet size: 9.7500” x 6.0000”

# of panels: 40

Paper used: 27# Pharmopaque

Rev.: 1

Date: 10/10/13

Part#: 5503

Customer Comments/Instructions:

Please indicate status below. Please sign, date, and return if approved.

☐ REVISE AND RE-PROOF  ☐ APPROVED

APPROVAL SIGNATURE

DATE: 

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PLATINUM PRESS INC. Healthcare Packaging

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PHOSPHA 250™ NEUTRAL

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, 296 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.

PHOSPHA 250™ NEUTRAL increases urinary phosphate and:

INDICATIONS AND USAGE
Oral administration of inorganic phosphates increases serum phosphate levels. Phosphates lower urinary calcium 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.

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
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.

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; hypocalcemia; hypotension; toxemia of pregnancy; hypophosphatemia; 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: 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. 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
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

Rx only

5503 Rev 10/13

IDENTITY: Phospha 250™ Neutral is an orally administered medical food for use only under medical supervision for the dietary management of hypophosphatemia.

Manufactured for:
Rising Pharmaceuticals, Inc.
3 Pearl Court
Allendale, NJ 07401

Manufactured by:
Mirror Pharmaceuticals LLC
Fairfield, NJ 07004