FIRST®- Pantoprazole ℞

Pantoprazole 4 mg/mL in FIRST-Mint Flavored Suspension Compounding Kit.

FOR PRESCRIPTION COMPOUNDING ONLY

DESCRIPTION

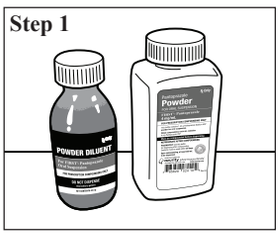
Each FIRST®-Pantoprazole Compounding Kit is comprised of bulk pantoprazole sodium USP powder and a bottle of a powder diluent blend containing benzyl alcohol, calcium carbonate, CL-611 (microcrystalline cellulose and carboxymethylcellulose sodium), colloidal silicon dioxide, peppermint flavoring, potassium acesulfame, sodium stearyl fumarate, sucralose, trisodium phosphate dodecahydrate.* The bottles will be combined at the pharmacy and reconstituted with purified water prior to dispensing. When compounded, the final product provides a homogeneous suspension containing 4 mg/mL pantoprazole.

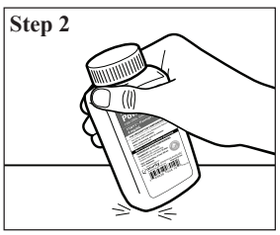
HOW SUPPLIED AND COMPOUNDING DIRECTIONS

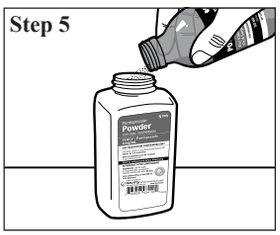
Component	Product Code	Quantity
FIRST Pantoprazole Compounding Kit	65628-024-10	1 carton
Powder Diluent	65628-023-10	44.5 g
Bulk Pantoprazole Sodium USP Powder	65628-022-10	1.43 g

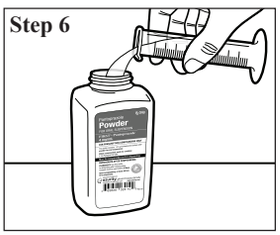
TO THE PHARMACIST

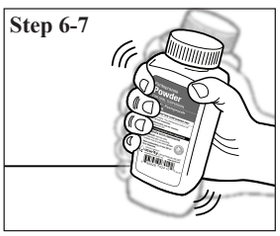
Everything you need to make this prescription is included.
Please note that these illustrations may not be representative of the product supplied and do not depict all steps listed below. Please refer to the actual bottle labels for contents and compounded concentration.











1. FIRST®-Pantoprazole Compounding Kit contains pre-measured pantoprazole powder and a bottle of powder diluent.
2. Hold the neck of the bottle containing the pantoprazole powder and tap the bottom edges on a hard surface to loosen the powder. Remove the cap from the bottle.
3. Lightly shake DILUENT bottle, and tap the top of the cap to remove powder. Open the bottle.
4. Tap the top of the induction seal liner on the pantoprazole bottle. Carefully and slowly peel back the inner foil seal liner on the bottle. Scrape any powder from the seal into the pantoprazole bottle.
5. Carefully empty the contents of the DILUENT bottle into the pantoprazole powder bottle tapping the sides to empty as much powder as possible.
6. Measure 290 mL of purified water in a graduated cylinder. Add approximately half of the 290 mL purified water to the pantoprazole powder bottle and replace the cap. Shake the pantoprazole powder bottle vigorously for approximately 30 seconds. Add the rest of the purified water in the graduated cylinder to the pantoprazole powder bottle and replace the cap. Shake the pantoprazole powder bottle vigorously for approximately 30 seconds.
7. Instruct patient to shake the bottle well before use. Label the product with the appropriate auxiliary labels including but not limited to: **SHAKE WELL** and **REFRIGERATE**.
8. If appropriate, dispense enclosed adapter cap and oral syringe with accompanied instructions for use. Instruct patient in use of dispensed compounded suspension with enclosed adapter cap and oral syringe.

WARNING: ADAPTER CAP IS NOT CHILD-RESISTANT.

WARNINGS AND PRECAUTIONS:

Cutaneous and Systemic Lupus Erythematosus (CLE and SLE): Avoid administration of proton pump inhibitors (PPIs) for longer than medically indicated. If signs or symptoms are consistent with CLE or SLE are noted in patients receiving pantoprazole, discontinue the drug and refer the patient to the appropriate specialist for evaluation.

***Clostridium difficile*-Associated Diarrhea:** Use of pantoprazole may be associated with an increased risk of *Clostridium difficile*-associated diarrhea, especially in hospitalized patients.

Concurrent Gastric Malignancy: Symptomatic response to therapy with pantoprazole does not preclude the presence of gastric malignancy.

Atrophic gastritis has been noted with long-term therapy.

Bone Fracture: Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine.

Fundic Gland Polyps: PPI use is associated with an increased risk of fundic gland polyps.

Hypomagnesemia: Reported rarely with prolonged treatment with PPIs.

Cyanocobalamin (Vitamin B-12) Deficiency: Daily long-term use (e.g., longer than 3 years) may lead to malabsorption or a deficiency of cyanocobalamin.

Tumorigenicity: Due to the chronic nature of GERD, there may be a potential for prolonged administration of pantoprazole. In long-term rodent studies, pantoprazole was carcinogenic and caused rare types of gastrointestinal tumors. The relevance of these findings to tumor development in humans is unknown.

Concurrent Gastric Malignancy: Symptomatic response to therapy with pantoprazole does not preclude the presence of gastric malignancy.

Acute Tubulointerstitial Nephritis: Acute tubulointerstitial nephritis (TIN) has been observed in patients taking PPIs and may occur at any point during PPI therapy.

STABILITY/STORAGE/BEYOND-USE DATE INFORMATION

Compounded FIRST®-Pantoprazole Suspension meets USP <51>, Antimicrobial Effectiveness Testing.**

Prior to compounding, store FIRST®-Pantoprazole Compounding Kit at 20°C-25°C (68°F-77°F); excursions permitted between 15°C-30°C (59°-86°F) [see USP Controlled Room Temperature]. Store final *compounded* product at refrigerated temperature 2°C-8°C (36°F-46°F).

For oral use only. Avoid contact with eyes. Keep container tightly closed. Keep out of the reach of children. Protect from light. Protect from freezing. The beyond-use date of the compounded product, as dispensed, when stored at refrigerated temperature is ***not later than 30 days***.

HOW SUPPLIED

The FIRST®-Pantoprazole Compounding Kits is available as follows:
316 mL as dispensed: 65628-024-10 ***

*Certificate of analysis on file.
**Data and documentation on file.
***Upon compounding, bottle will contain an overage to account for product loss during administration. The overage is to ensure that a minimum of 300 mL is supplied to the patient for a month supply.

For additional information or questions, please contact us: 800-461-7449, or e-mail us at customerservice@azurity.com.

℞ ONLY

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Manufactured for:
azurity® pharmaceuticals
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Mint Flavor

ORAL SUSPENSION

This product's labeling may have been updated. For current Package Insert, please visit www.firstkits.com/pantoprazole.
PN: 65628-0275
Rev: 03