

Patient Name: _____

Date Prepared: _____

Compounding Formulation Record

Rx: _____ - _____

Recipe ID#: _____ (IF AVAILABLE)

Batch #: _____ Beyond Use Date: 30 Days Good For Use Until: ____/____/____

Compounding Formulation Record for: FIRST®-Pantoprazole 4 mg/mL Suspension

CLASS: RX DOSAGE FORM: Suspension ROUTE OF ADMINISTRATION: Oral

Ingredient Name	Dispensed Quantity	Product Code	Manufacturer	Lot #	Exp. Date of Ingredient	Prepared By:	Verified By:
Bulk Pantoprazole Sodium USP Powder	1.43 g	65628-022-10	Azurity				
Powder Diluent	44.5 g	65628-023-10	Azurity				
Purified Water	290 mL						
Prior to compounding, store FIRST®-Pantoprazole Compounding Kit at room temperature 20°C - 25°C (68°F - 77°F) Store final compounded product at refrigerated temperature 2°C - 8°C (36°F - 46°F)							
FIRST®-Pantoprazole 300 mL Kit (65628-024-10) contains 1.43 g Pantoprazole Sodium USP Powder + 44.5 g Powder Diluent							
Total Quantity	300 mL						

SEE FULL PACKAGE INSERT FOR ADDITIONAL INFORMATION. THE RECORD DOES NOT INCLUDE ALL THE INFORMATION NEEDED TO USE THE PRODUCT SAFELY AND EFFECTIVELY.

COMPOUNDING INSTRUCTIONS:

- FIRST®-Pantoprazole Compounding Kit contains pre-measured pantoprazole powder and a bottle of powder diluent.
- 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.
- Lightly shake DILUENT bottle, and tap the top of the cap to remove powder. Open the bottle.
- 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.
- Carefully empty the contents of the DILUENT bottle into the pantoprazole powder bottle tapping the sides to empty as much powder as possible.
- 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.
- 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**.
- 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.**

AUXILIARY LABELS:

- 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**.

REFERENCE:

FIRST® - Pantoprazole 4 mg/mL [PACKAGE INSERT].
Woburn, MA: Azurity Pharmaceuticals, Inc. 2023
PART CMP-685 | REV. 03

