

Patient Name: _____

Date Prepared: _____

Rx: _____

Compounding Formulation Record

Recipe ID#: _____ (IF AVAILABLE)

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

Compounding Formulation Record for: FIRST®-Lansoprazole 3 mg/mL Suspension

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

Ingredient Name	Dispensed Quantity	NDC/UPC #	Manufacturer	Lot #	Exp. Date of Ingredient	Prepared By:	Verified By:
Lansoprazole Powder		65628-080-	Azurity				
FIRST® - PPI Suspension		65628-080-	Azurity				
Prior to compounding, store FIRST®-Lansoprazole Compounding Kit at room temperature 15°C - 30°C (59°F - 86°F) Store the final compounded formulation at refrigerated temperature 2° - 8°C (36° - 46°F)							
FIRST®-Lansoprazole 3 FL OZ (90 mL) Kit (NDC 65628-080-03) contains 0.27 g Lansoprazole Powder + 90 mL FIRST® PPI Suspension							
FIRST®-Lansoprazole 5 FL OZ (150 mL) Kit (NDC 65628-080-05) contains 0.45 g Lansoprazole Powder + 150 mL FIRST® PPI Suspension							
FIRST®-Lansoprazole 10 FL OZ (300 mL) Kit (NDC 65628-080-10) contains 0.9 g Lansoprazole Powder + 300 mL FIRST® PPI Suspension							
Total Quantity	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®-Lansoprazole Compounding Kit contains pre-measured lansoprazole powder and FIRST® - PPI Suspension.

1. FIRST®- Lansoprazole Compounding Kit contains pre-measured lansoprazole powder and FIRST® - PPI Suspension.
2. Hold the neck of the bottle containing the lansoprazole powder and tap the bottom edges on a hard surface to loosen the powder. Remove the cap from the bottle.
3. Tap the top of the induction seal liner to loosen any powder which may have adhered to the liner. Carefully and slowly peel back the inner foil seal liner from the bottle. Using the enclosed tool, scrape any lansoprazole powder from the seal into the bottle. Now using the smaller end of the tool, with firm strength loosen any powder from the inside lower edges of the bottle. **It is important to make sure that no lansoprazole powder remains trapped in the inside lower edges of the bottle.** Again using the tool distribute the lansoprazole powder evenly over the bottom surface of the bottle.

4. Shake the FIRST® - PPI Suspension bottle for a few seconds. Open the suspension bottle and empty about half the contents of the FIRST®- PPI Suspension bottle **into the lansoprazole powder bottle**. Replace the cap and shake the lansoprazole powder bottle for approximately 60 seconds. Shake vigorously.
5. Empty the remaining FIRST®- PPI Suspension **into the lansoprazole powder bottle. Allow suspension to drain for 10 seconds.** Replace the cap and shake the lansoprazole powder bottle for approximately 60 seconds. Shake vigorously.
6. **Instruct patient to shake the bottle well before each use.**
7. If appropriate, dispense enclosed adapter cap and oral syringe with accompanying 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® - LANSOPRAZOLE 3 MG/ML [PACKAGE INSERT].
Wilmington, MA: Azurity Pharmaceuticals, Inc. 2020
PART CMP-688 | REV. 00

