

FIRST®-Lansoprazole R

Lansoprazole 3 mg/mL in FIRST®- Suspension Compounding Kit

Non-FDA Approved Compounding Kit: For Pharmacist Use Only

DESCRIPTION

Each FIRST®-Lansoprazole Compounding Kit is comprised of bulk lansoprazole powder USP and FIRST®-Suspension containing ammonium glycyrrhizate, benzyl alcohol, FD&C Red No. 40, poloxamer 188, propylene glycol, purified water, simethicone emulsion, sodium bicarbonate, sodium citrate (dihydrate), strawberry flavor, sucralose, and xanthan gum.* **This product contains ingredients that are derived from corn.** When compounded, the final product provides an homogenous suspension containing 3 mg per mL of lansoprazole.

Size	3 FL OZ	5 FL OZ	10 FL OZ
Product Code	65628-080-03	65628-080-05	65628-080-10
Bulk Lansoprazole USP Powder	0.27 g	0.45 g	0.9 g
FIRST®-Suspension	90 mL	150 mL	300 mL

COMPOUNDING DIRECTIONS:



1. FIRST®-Lansoprazole Compounding Kit contains pre-measured lansoprazole powder and FIRST®-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.

4. Shake the FIRST®-Suspension bottle for a few seconds. Open the suspension bottle and empty about one-third the contents of the FIRST®-Suspension bottle **into the lansoprazole powder bottle**. Replace the cap and shake the lansoprazole powder bottle for approximately 30 seconds. Shake vigorously.



5. Empty another one-third of the contents of FIRST®-Suspension **into the lansoprazole powder bottle**. Replace the cap and shake the lansoprazole powder bottle for approximately 30 seconds. Shake vigorously.

6. Empty the remaining FIRST®-Suspension **into the lansoprazole powder bottle**. Allow suspension to drain for 10 seconds. Replace the cap and shake the lansoprazole powder bottle for approximately 30 seconds. Shake vigorously.

7. Shake the bottle well before each use.

8. If appropriate, dispense enclosed adapter cap and oral syringe with accompanying instructions for use.

WARNING: ADAPTER CAP IS NOT CHILD-RESISTANT.

Prior to compounding, store FIRST®-Lansoprazole Compounding Kit at refrigerated temperature 2°C - 8°C (36°F - 46°F).

Based on real time temperature and humidity testing, *compounded* FIRST®-Lansoprazole product is stable for at least 30 days at refrigerated temperature 2°C - 8°C (36°F - 46°F) [see USP].** Store the final *compounded* formulation 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**.

FIRST®-Lansoprazole Compounding Kits are available as follows:

3 FL OZ (90 mL) as dispensed	65628-080-03
Bulk Lansoprazole USP Powder	65628-081-03
FIRST®-Suspension	65628-082-03
5 FL OZ (150 mL) as dispensed	65628-080-05
Bulk Lansoprazole USP Powder	65628-081-05
FIRST®-Suspension	65628-082-05
10 FL OZ (300 mL) as dispensed	65628-080-10
Bulk Lansoprazole USP Powder	65628-081-10
FIRST®-Suspension	65628-082-10

* Certificate of analysis on file

** Data and documentation on file

R ONLY

Revised: October 2024

Manufactured for:

 **azurity**[®]
pharmaceuticals
Woburn, MA 01801 USA
www.azurity.com


Strawberry
Flavor



65628-00303

REV: 08