FIRST®- Lansoprazole ℞

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

FOR PRESCRIPTION COMPOUNDING ONLY

DESCRIPTION

Each FIRST®- Lansoprazole Compounding Kit is comprised of lansoprazole powder USP and FIRST®- PPI (Proton Pump Inhibitor) Suspension containing artificial strawberry flavor, benzyl alcohol, FD&C Red #40, Magnasweet® 100 (ammonium glycyrrhizate), poloxamer 188, propylene glycol, purified water, simethicone emulsion, sodium bicarbonate, sodium citrate (dihydrate), 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 in FIRST®- PPI Suspension comparable to the active ingredient in *Simplified Lansoprazole Suspension (SLS).***

How Supplied and Compounding Directions

Size	10 FL OZ	5 FL OZ	3 FL OZ
NDC#	65628-080-10	65628-080-05	65628-080-03
Lansoprazole Powder	0.9 g	0.45 g	0.27 g
FIRST®- PPI Suspension	300 mL	150 mL	90 mL

TO THE PHARMACIST

Everything you need to make this ℞ is included...

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.**

WARNINGS AND PRECAUTIONS:

Bone Fractures. People who are taking multiple daily doses of proton pump inhibitors for a long period of time may have an increased risk of fractures of the hip, wrist, or spine.

Low magnesium levels in the body. This problem can be serious. Low magnesium can happen in some people who take proton pump inhibitors for at least 3 months. If low magnesium levels happen, it is usually after a year of treatment.

***Clostridium difficile*-associated diarrhea.** Long-term use of proton pump inhibitors may increase the risk of diarrhea caused by *Clostridium difficile*, especially in hospitalized patients.

FIRST®- Lansoprazole Compounding Kit components have a two-year expiration date.** Prior to compounding, store FIRST®- Lansoprazole Compounding Kit at room temperature 15º-30ºC (59º-86ºF).

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

FIRST®- PPI Suspension meets the requirements for total aerobic microbial count of not more than 100 cfu/mL, as well as for the absence of the specified microorganisms *Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus,* and *Salmonella spp,* when tested as described in the current USP under <61> Microbial Enumeration Tests and <62> Tests for Specified Microorganisms. FIRST®- PPI Suspension also meets the requirements as described in the current USP under <51> Antimicrobial Effectiveness Testing for Category 3 products.

When compounded and stored according to instructions, acid neutralizing capacity is maintained for at least 30 days.**

Compendial difference: "Other individual impurity" (per USP) in lansoprazole powder exceeded current USP specifications following storage at room temperature (25ºC ± 2ºC) at six to twenty-four months. However the biological safety of this impurity has been established through an acute toxicity study performed with impurity-spiked lansoprazole powder. The study showed no sign of toxicity and indicated an acute oral LD_{50} of >5000mg/kg. Report on file.

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

FIRST®- Lansoprazole Compounding Kits are available as follows:

3 FL OZ (90 mL) as dispensed	NDC 65628-080-03
5 FL OZ (150 mL) as dispensed	NDC 65628-080-05
10 FL OZ (300 mL) as dispensed	NDC 65628-080-10

* Certificate of analysis on file
** Data and documentation on file

℞ONLY

Revised: November 2016
U.S. Patent Pending

Manufactured for:

CUTISPHARMA®
Transforming Compounding through Innovation™

Wilmington, MA 01887, USA www.cutispharma.com

Strawberry Flavor

ORAL SUSPENSION®

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