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, benzoic acid, FD&C Red 40, Magnesium® 100 (ammonium glycyrrhizinate), polysorbate 18, propylene glycol, purified water, sirupfomone emulsion, sodium bicarbonate, sodium citrate (phosphate), sucrose, and xanthan gum. This product contains ingredients that are derived from corn. When compounded, the final product provides a homogenous suspension containing 3 mg per mL of lansoprazole in FIRST®-PPI Suspension compatible to the active ingredient in Simplified Lansoprazole Suspension (SL®).

How Supplied and Compounding Directions

<table>
<thead>
<tr>
<th>Size</th>
<th>10 FL OZ</th>
<th>5 FL OZ</th>
<th>3 FL OZ</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDC#</td>
<td>65628-496-10</td>
<td>65628-080-05</td>
<td>65628-080-03</td>
</tr>
<tr>
<td>Lansoprazole Powder</td>
<td>0.0 g</td>
<td>0.45 g</td>
<td>0.27 g</td>
</tr>
<tr>
<td>FIRST®-PPI Suspension</td>
<td>100 mL</td>
<td>150 mL</td>
<td>90 mL</td>
</tr>
</tbody>
</table>

TO THE PHARMACIST
Everything you need to make this kit 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 tip the bottle edges on a hard surface to loosen the powder. Remove the cap from the bottle.
3. Tap the top of the induction seal firmly to loosen any powder which may have adhered to it. 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 pressure, 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 drize 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 dispensing compounded suspension with enclosed adapter cap and oral syringe.

WARNING: ADAPTER CAP IS NOT CHILD-RESISTANT.

WARNINGS AND PRECAUTIONS:
Bone Fractures. Patients 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 severe. Low magnesium levels in the body can make it harder for some patients to take proton pump inhibitors for at least 3 months. If low magnesium levels become a problem, it usually occurs after a year of treatment.
Celiac disease-associated diarrhea. Long-term use of proton pump inhibitors may increase the risk of diarrhea caused by Celiac disease, especially in hospitalized patients.
FIRST®-Lansoprazole Compounding Kit contains a 2-year expiration date.** Prior to compounding, store FIRST®-Lansoprazole Compounding Kit at room temperature 15°-30°C (59°-86°F).

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

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

Compositional difference: "Other impurities/impurity" per USP in lansoprazole powder exceeds current USP specifications following storage at room temperature (25°C ± 3°C) for ten years (first year). However, the biological safety of this impurity has been established through an acute toxicity study performed with impurity-modified lansoprazole powder. The study showed no sign of toxicity and indicated an acute oral LD50 of 4,094 mg/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 65628-200-05
5 FL OZ (150 mL) as dispensed NDC 65628-200-05
10 FL OZ (300 mL) as dispensed NDC 65628-400-10

* Controls of analysis on file.
** Data and documentation on file.

RESOLVED: April 2019
U.S. Patent Pending

Manufactured for:
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