

# FIRST®-Omeprazole R

## Omeprazole 2 mg/mL in FIRST®-PPI Suspension Compounding Kit

**FOR PRESCRIPTION COMPOUNDING ONLY**

### DESCRIPTION

Each FIRST®-Omeprazole Compounding Kit is comprised of omeprazole 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 2 mg per mL of omeprazole in FIRST®-PPI Suspension comparable to the active ingredient in *Simplified Omeprazole Suspension (SOS)*.\*\*

### How Supplied and Compounding Directions

| Size                  | 10 FL OZ     | 5 FL OZ      | 3 FL OZ      |
|-----------------------|--------------|--------------|--------------|
| NDC#                  | 65628-070-10 | 65628-070-05 | 65628-070-03 |
| Omeprazole Powder     | 0.6 g        | 0.3 g        | 0.18 g       |
| FIRST®-PPI Suspension | 300 mL       | 150 mL       | 90 mL        |

### TO THE PHARMACIST

*Everything you need to make this R is included...*



1. FIRST®-Omeprazole Compounding Kit contains pre-measured omeprazole powder and FIRST® - PPI Suspension.
2. Hold the neck of the bottle containing the omeprazole 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 omeprazole 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 omeprazole powder remains trapped in the inside lower edges of the bottle.*** Again using the tool, distribute the omeprazole 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 omeprazole powder bottle.*** Replace the cap and shake the omeprazole powder bottle for approximately 60 seconds. Shake vigorously.
5. Empty the remaining FIRST®- PPI Suspension ***into the omeprazole powder bottle.*** Allow suspension to drain for 10 seconds. Replace the cap and shake the Omeprazole powder bottle for approximately 30 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 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.**

## 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.

**Atrophic gastritis.** This condition has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole.

Prior to compounding, store FIRST®-Omeprazole Compounding Kit at refrigerated temperature 2°-8°C (36°-46°F) [see USP].

Based on real time temperature and humidity testing, *compounded* FIRST®-Omeprazole 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).

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.\*\*

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®-Omeprazole Compounding Kits are available as follows:

|                                |                  |
|--------------------------------|------------------|
| 3 FL OZ (90 mL) as dispensed   | NDC 65628-070-03 |
| 5 FL OZ (150 mL) as dispensed  | NDC 65628-070-05 |
| 10 FL OZ (300 mL) as dispensed | NDC 65628-070-10 |

\* Certificate of analysis on file

\*\* Data and documentation on file

# R&ONLY

Revised: October 2016

U.S. Patent Pending

Manufactured for:



Wilmington, MA 01887, USA [www.cutispharma.com](http://www.cutispharma.com)



REV 1