## FIRST°- Omeprazole R

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

Non-FDA Approved Compounding Kit: For Pharmacist Use Only

## **DESCRIPTION**

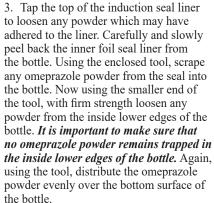
Each FIRST®-Omeprazole Compounding Kit is comprised of bulk omeprazole powder USP and FIRST®- Suspension containing ammonium glycyrrhizate, benzyl alcohol, FD&C Red No. 40, poloxamer 188, propylene glycol, purified water, simethicone emulsion, sodium bicarbonate, sodium citrate (dihydrate), strawberry flavor, sucralose, and xanthan gum.\* This product contains ingredients that are derived from corn. When compounded, the final product provides a homogenous suspension containing 2 mg per mL of omeprazole.

Size	3 FL OZ	5 FL OZ	10 FL OZ
Product Code	65628-070-03	65628-070-05	65628-070-10
Bulk Omeprazole USP Powder	0.18 g	0.3 g	0.6 g
FIRST®- Suspension	90 mL	150 mL	300 mL

## **COMPOUNDING DIRECTIONS:**



- 1. FIRST®-Omeprazole Compounding Kit contains pre-measured omeprazole powder and FIRST®-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.





4. Shake the FIRST®-Suspension bottle for a few seconds. Open the suspension bottle and empty about half the contents of the FIRST®- 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®-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. Shake the bottle well before each use.

7. If appropriate, dispense enclosed adapter cap and oral syringe with accompanied instructions for use.

WARNING: ADAPTER CAP IS NOT CHILD-RESISTANT.

Prior to compounding, store FIRST\*-Omeprazole Compounding Kit at refrigerated temperature 2°C-8°C (36°F-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  $2^{\circ}\text{C}$  -  $8^{\circ}\text{C}$  ( $36^{\circ}\text{F}$  -  $46^{\circ}\text{F}$ ) [see USP].\*\* Store the final *compounded* formulation at refrigerated temperature  $2^{\circ}\text{C}$  -  $8^{\circ}\text{C}$  ( $36^{\circ}\text{F}$  -  $46^{\circ}\text{F}$ ).

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®-Omeprazole Compounding Kits are available as follows:

3 FL OZ (90 mL) as dispensed	65628-070-03
Bulk Omeprazole USP Powder	65628-071-03
FIRST®-Suspension	65628-072-03
5 FL OZ (150 mL) as dispensed	65628-070-05
Bulk Omeprazole USP Powder	65628-071-05
FIRST*-Suspension	65628-072-05
10 FL OZ (300 mL) as dispensed	65628-070-10
Bulk Omeprazole USP Powder	65628-071-10
FIRST®-Suspension	65628-072-10

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

R ONLY

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