

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.

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®-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°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®-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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Manufactured for:



Woburn, MA 01801 USA www.azurity.com



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