

Compounding Formulation Record for: FIRST®-Omeprazole 2 mg/mL - Suspension Compounding Kit

Non-FDA Approved Compounding Kit: For Pharmacist Use Only

Patient Name: _____

Date Prepared: _____

Rx: _____ - _____

Batch #: _____ Beyond Use Date: 30 Days Good For Use Until: ____/____/____

CLASS: RX **DOSAGE FORM:** Suspension **ROUTE OF ADMINISTRATION:** Oral

Ingredient Name	Dispensed Quantity	Product Code	Manufacturer	Lot #	Exp. Date of Ingredient	Prepared By:	Verified By:
Bulk Omeprazole USP Powder		65628-071-	Azurity				
FIRST® - Suspension		65628-072-	Azurity				
Prior to compounding, store FIRST®-Omeprazole Compounding Kit at refrigerated temperature 2°C - 8°C (36°F - 46°F) Store the final compounded formulation at refrigerated temperature 2°C - 8°C (36°F - 46°F)							
FIRST®-Omeprazole 3 FL OZ (90 mL) Kit (65628-070-03) contains 0.18 g Bulk Omeprazole USP Powder + 90 mL FIRST® Suspension							
FIRST®-Omeprazole 5 FL OZ (150 mL) Kit (65628-070-05) contains 0.3 g Bulk Omeprazole USP Powder + 150 mL FIRST® Suspension							
FIRST®-Omeprazole 10 FL OZ (150 mL) Kit (65628-070-10) contains 0.6 g Bulk Omeprazole USP Powder + 300 mL FIRST® Suspension							
Total Quantity	mL						

SEE PHARMACIST COMPOUNDING INSTRUCTIONS FOR ADDITIONAL INFORMATION.

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.

RECOMMENDED AUXILIARY LABELS:

- 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.**

REFERENCE:

FIRST® - OMEPRAZOLE 2MG/ML [PHARMACIST COMPOUNDING INSTRUCTIONS]
 Woburn, MA: Azurity Pharmaceuticals, Inc. 2024
PART CMP-689 | REV. 02

