

Patient Name: \_\_\_\_\_

Date Prepared: \_\_\_\_\_

Rx : \_\_\_\_\_ - \_\_\_\_\_

Recipe ID#: \_\_\_\_\_ (IF AVAILABLE)

### Compounding Formulation Record

Batch #: \_\_\_\_\_ Beyond Use Date: 30 Days Good For Use Until: \_\_\_\_/\_\_\_\_/\_\_\_\_

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

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® - PPI Suspension   |                    | 65628-072-   | Azurity      |       |                         |              |              |
| <b>Prior to compounding, store FIRST®-Omeprazole Compounding Kit at refrigerated temperature 2°C - 8°C (36°F - 46°F)<br/>Store the final compounded formulation at refrigerated temperature 2°C - 8°C (36°F - 46°F)</b> |                    |              |              |       |                         |              |              |
| <b>FIRST®-Omeprazole 3 FL OZ (90 mL) Kit (65628-070-03) contains 0.18 g Omeprazole USP Powder + 90 mL FIRST® PPI Suspension</b>   |                    |              |              |       |                         |              |              |
| <b>FIRST®-Omeprazole 5 FL OZ (150 mL) Kit (65628-070-05) contains 0.3 g Omeprazole USP Powder + 150 mL FIRST® PPI Suspension</b>  |                    |              |              |       |                         |              |              |
| <b>FIRST®-Omeprazole 10 FL OZ (300 mL) Kit (65628-070-10) contains 0.6 g Omeprazole USP Powder + 300 mL FIRST® PPI Suspension</b>   |                    |              |              |       |                         |              |              |
| Total Quantity  | mL                 |              |              |       |                         |              |              |

SEE FULL PACKAGE INSERT FOR ADDITIONAL INFORMATION. THE RECORD DOES NOT INCLUDE ALL THE INFORMATION NEEDED TO USE THE PRODUCT SAFELY AND EFFECTIVELY.

#### COMPOUNDING INSTRUCTIONS:

- FIRST®-Omeprazole Compounding Kit contains pre-measured omeprazole powder and FIRST®-PPI Suspension.
- 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.
- 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.
- 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.
- 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.
- Instruct patient to shake the bottle well before each use.**
- 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 & PRECAUTIONS:

- Bone fractures
- Low magnesium levels in the body
- Clostridium difficile-associated diarrhea
- Atrophic gastritis

#### 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 [PACKAGE INSERT].  
 Woburn, MA: Azurity Pharmaceuticals, Inc. 2023  
**PART CMP-689 | REV. 01**

