

Patient Name: _____

Date Prepared: _____

Compounding Formulation Record

Rx: _____ - _____

Recipe ID#: _____ (IF AVAILABLE)

Batch #: _____ Beyond Use Date: 180 Days Good For Use Until: ____/____/____

Compounding Formulation Record for: FIRST®-Mouthwash BLM Suspension

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

| Ingredient Name | Dispensed Quantity | NDC/UPC # | Manufacturer | Lot # | Exp. Date of Ingredient | Prepared By: | Verified By: |
|--|--------------------|------------|--------------|-------|-------------------------|--------------|--------------|
| Diphenhydramine HCl | | 65628-050- | Azurity | | | | |
| Lidocaine HCl | | 65628-050- | Azurity | | | | |
| FIRST®-Mouthwash Suspension | | 65628-050- | Azurity | | | | |
| Prior to compounding, store FIRST®-Mouthwash BLM Compounding Kit at room temperature 15°C - 30°C (59°F - 86°F) Store final formulation at room temperature, 15°C - 30°C (59°F - 86°F) for no later than 180 days. | | | | | | | |
| FIRST®-Mouthwash BLM 4 FL OZ (119 mL) Kit (NDC 65628-050-04) contains 0.1 g Diphenhydramine HCl + 0.8 g Lidocaine HCl + 119 mL FIRST®-Mouthwash Suspension | | | | | | | |
| FIRST®-Mouthwash BLM 8 FL OZ (237 mL) Kit (NDC 65628-050-01) contains 0.2 g Diphenhydramine HCl + 1.6 g Lidocaine HCl + 237 mL FIRST®-Mouthwash Suspension | | | | | | | |
| 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®- Mouthwash BLM Compounding Kit contains premeasured diphenhydramine hydrochloride powder, lidocaine hydrochloride powder, and mouthwash suspension (aluminum hydroxide, magnesium hydroxide, simethicone plus inactive ingredients).
- Important** - Before dispensing, with your finger, tap the top and bottom of the lidocaine hydrochloride bottle. Open the suspension bottle and empty the lidocaine hydrochloride powder into the suspension. With your finger, tap the top and bottom of the diphenhydramine hydrochloride bottle. Due to the hygroscopic nature and small

- volume of the powder, remove the cap and use the enclosed spatula to empty the contents into the mouthwash suspension. Close the suspension bottle and shake it vertically for approximately 20-30 seconds. The appropriate quantities of diphenhydramine hydrochloride powder and lidocaine hydrochloride powder have been packaged in each bottle to deliver the required dosage of each drug. Residual quantities remaining in the bottles after emptying need not be rinsed out.
- Instruct the patient to shake bottle well before each use.

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 room temperature is **not later than 180 days**.

REFERENCE:

FIRST® - Mouthwash BLM [PACKAGE INSERT].
Wilmington, MA: Azurity Pharmaceuticals, Inc. 2020
PART CMP-686 | REV. 01

