

# Compounding Formulation Record for: FIRST®-Mouthwash BLM Suspension Compounding Kit

## Non-FDA Approved Compounding Kit: For Pharmacist Use Only

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

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

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

Batch #: \_\_\_\_\_ Beyond Use Date: 180 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 Diphenhydramine HCl USP Powder		65628-05	Azurity				
Bulk Lidocaine HCl USP Powder		65628-05	Azurity				
FIRST®-Mouthwash Suspension		65628-05	Azurity				
<b>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.</b>							
FIRST®-Mouthwash BLM 4 FL OZ (119 mL) Kit (65628-050-04) contains 0.1 g Bulk Diphenhydramine HCl USP Powder + 0.8 g Bulk Lidocaine HCl USP Powder + 118 mL FIRST®-Mouthwash Suspension							
FIRST®-Mouthwash BLM 8 FL OZ (237 mL) Kit (65628-050-01) contains 0.2 g Bulk Diphenhydramine HCl USP Powder + 1.6 g Bulk Lidocaine HCl USP Powder + 236 mL FIRST®-Mouthwash Suspension							
Total Quantity	mL						

### SEE PHARMACIST COMPOUNDING INSTRUCTIONS FOR ADDITIONAL INFORMATION.

#### COMPOUNDING DIRECTIONS:

- 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.
- Shake bottle well before each use.

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

#### REFERENCE:

FIRST® - Mouthwash BLM [PHARMACIST COMPOUNDING INSTRUCTIONS]  
Woburn, MA: Azurity Pharmaceuticals, Inc. 2024  
**PART CMP-686 | REV. 03**

