

# FIRST® Mouthwash BLM R

**Diphenhydramine HCl, Lidocaine HCl, Aluminum Hydroxide, Magnesium Hydroxide, and Simethicone Compounding Kit**

## FOR PRESCRIPTION COMPOUNDING ONLY

### DESCRIPTION

Each FIRST®- Mouthwash BLM Compounding Kit is comprised of diphenhydramine hydrochloride powder USP and lidocaine hydrochloride powder USP for oral use.\* FIRST®- Mouthwash BLM Compounding Kit also contains a suspension containing aluminum hydroxide USP (equivalent to dried gel USP), magnesium hydroxide USP, and simethicone USP with artificial cherry flavor, benzyl alcohol, butylparaben, D&C red #28, FD&C red #40, hydroxyethylcellulose, Magnasweet® 185, propylparaben, purified water, saccharin sodium, and sorbitol solution (corn-derived).\* When compounded, the final product provides a homogeneous suspension containing diphenhydramine hydrochloride, lidocaine hydrochloride, and aluminum hydroxide, magnesium hydroxide, and simethicone comparable to the active ingredients (Benadryl®, Lidocaine HCl 2% Viscous, Maalox® 1:1:1) contained in *Magic Mouthwash*.\*\*

### How Supplied and Compounding Directions

Size	4 FL OZ	8 FL OZ
NDC#	65628-050-04	65628-050-01
Diphenhydramine HCl	0.1 g	0.2 g
Lidocaine HCl	0.8 g	1.6 g
FIRST®- Mouthwash Suspension	118 mL	236 mL

### TO THE PHARMACIST

**Everything you need to make this R is included...**



1. FIRST®- Mouthwash BLM Compounding Kit contains premeasured diphenhydramine hydrochloride powder, lidocaine hydrochloride powder, and mouthwash suspension (aluminum hydroxide, magnesium hydroxide, simethicone plus inactive ingredients).

2. **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 vigorously 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.

3. Instruct the patient to shake bottle well before each use.



Prior to compounding, store FIRST®- Mouthwash BLM Compounding Kit at room temperature between 15°–30°C (59°–86°F) [see USP]. Also store final formulation at room temperature, 15°–30°C (59°–86°F).

FIRST®- Mouthwash BLM Compounding Kit components have a two-year expiration date.\*\*\* Based on real time controlled room temperature and humidity testing, compounded FIRST®- Mouthwash BLM Compounding product is stable for at least six months.\*\*\*

Compendial difference: "Loss on drying" in diphenhydramine hydrochloride powder exceeded current USP specifications following storage at accelerated conditions (40°C ± 2°C/75 ± 5% RH) at 3 months. However, the chemical assay and organic impurities per USP are not impacted as seen at 3 month accelerated (40°C ± 2°C/75 ± 5% RH) conditions. Report on file. All current USP specifications including loss on drying are met following long term storage conditions (25°C ± 2°C/60 ± 5% RH).

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**.

### How Supplied

FIRST®- Mouthwash BLM Compounding Kit are available as follows:

8 FL OZ (237 mL) as dispensed (NDC 65628-050-01)

4 FL OZ (119 mL) as dispensed (NDC 65628-050-04)

\* Certificate of Analysis on file

\*\* This product is not manufactured or distributed by Johnson & Johnson, a subsidiary of McNeil Consumer Healthcare, manufacturer of Benadryl® or by Novartis Consumer Health, Inc. manufacturer of Maalox®

\*\*\* Data and documentation on file

**R ONLY**

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Additional U.S. Patent Pending

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