

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 0.2 grams of diphenhydramine hydrochloride powder USP and 1.6 grams of lidocaine hydrochloride powder USP for oral use.* FIRST® - Mouthwash BLM Compounding Kit also contains a 236 mL suspension containing 3.15 grams of aluminum hydroxide USP (equivalent to dried gel USP), 3.15 grams of magnesium hydroxide USP, and 0.315 grams of simethicone USP with benzyl alcohol, butylparaben, flavor, hydroxyethylcellulose, propylparaben, purified water, saccharin sodium, sorbitol solution, D&C red #28, and FD&C red #40.* When compounded, the final product provides an 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	8 FL OZ (237 mL)
NDC#	65628-050-01
Diphenhydramine HCl	0.2 g
Lidocaine HCl	1.6 g
FIRST® - Mouthwash Suspension	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, tap the top and bottom of the bottle containing diphenhydramine hydrochloride to loosen the powder and remove the cap. Empty the diphenhydramine hydrochloride powder into the bottle containing the mouthwash liquid suspension. Likewise, tap the top and bottom of the bottle containing lidocaine hydrochloride to loosen the powder and remove the cap. Empty the lidocaine hydrochloride powder into the bottle containing the mouthwash liquid suspension. 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. Close the bottle and shake for 20 to 30 seconds. Instruct the patient to shake bottle well before each use.

Prior to compounding, store FIR&ST[®]- 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).

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

FIR&ST[®]- Mouthwash suspension meets the requirements for total aerobic microbial count of not more than 100 CFU/mL, as well as for the absence of USP designated pathogens (*Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella* spp.) when tested as described in the USP <61> Microbial Limit Tests.*** Both freshly prepared FIR&ST[®]- Mouthwash suspension samples and FIR&ST[®]- Mouthwash suspension samples which have been stored at accelerated ICH storage conditions (40±2°C/75%RH) meet the USP <51> requirements for Antimicrobial Effectiveness Testing, Category 4.***

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. Compounded product, as dispensed, is **stable for at least 180 days** at room temperature.

* Certificate of analysis on file

** This product is not manufactured by Pfizer, Inc., 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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