

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 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.*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 lidocaine hydrochloride bottle with your finger. Open the suspension bottle and empty the lidocaine hydrochloride powder into the suspension.

Likewise, tap the top and bottom of the diphenhydramine hydrochloride bottle with your finger. Remove the cap and because of the hygroscopic nature and small volume of the powder, using the enclosed spatula, 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 three-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.***

FIRST® - Mouthwash suspension meets the requirements for total aerobic microbial count of not more than 100 cfu/mL, as well as for the absence of the specified microorganisms *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella spp.* when tested as described in the current USP under <61> Microbial Enumeration Tests and <62> Tests for Specified Microorganisms. FIRST® - Mouthwash suspension also meets the requirements as described in the current USP under <51> Antimicrobial Effectiveness Testing for Category 4 products.

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.

How Supplied

FIRST® - Mouthwash BLM Compounding Kits 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 McNeil Consumer Healthcare, a Division of McNeil PPC, Inc., manufacturer of Benadryl® or by Novartis Consumer Health, Inc. manufacturer of Maalox®

*** Data and documentation on file

R ONLY

Revised: September 2016

U.S. Patent No. 6,708,822 B1

Additional U.S. Patent Pending



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