

# FIRST® - BXN Mouthwash R

Diphenhydramine, Lidocaine, and Nystatin  
Compounding Kit

**FOR PRESCRIPTION COMPOUNDING ONLY**

## DESCRIPTION

Each FIRST® - BXN Mouthwash Compounding Kit is comprised of 0.2 grams of diphenhydramine hydrochloride powder USP, 1.6 grams of lidocaine hydrochloride powder USP, and 1.6 grams of nystatin powder USP for oral use.\* FIRST® - BXN Mouthwash Compounding Kit also contains a 236 mL suspension containing benzyl alcohol, carboxymethylcellulose sodium, citric acid (anhydrous), dehydrated alcohol, FD&C yellow #5, flavors, propylene glycol, propylparaben, purified water, saccharin sodium, sodium citrate (dihydrate), and sorbitol solution. When compounded, the final product provides an homogeneous suspension containing diphenhydramine hydrochloride, lidocaine hydrochloride, and nystatin comparable to the active ingredients (Benadryl®, Xylocaine® 2% Viscous and Nystatin Oral Suspension 1: 1: 1 v/v/v) contained in *Magic Mouthwash with Nystatin*.\*\*

## How Supplied and Compounding Directions

Size	8 FL OZ (237 mL)
NDC#	65628-051-01
Diphenhydramine HCl	0.2 g
Lidocaine HCl	1.6 g
Nystatin	1.6 g
FIRST® - Mouthwash Suspension II	236 mL

## TO THE PHARMACIST

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



**TAP THE TOP**



**TAP THE BOTTOM**



**SHAKE HORIZONTALLY**



**SHAKE VERTICALLY**



1. FIRST® - Mouthwash BXN Compounding Kit contains premeasured diphenhydramine hydrochloride powder, lidocaine hydrochloride powder, nystatin powder, and Mouthwash Suspension II.

2. **Important** - Before compounding, shake the FIRST® - Mouthwash Suspension II bottle for a few seconds.

Tap the top and bottom of the nystatin bottle to loosen the powder. Remove the cap and empty the nystatin powder into the mouthwash suspension. Close the suspension bottle and **gently shake it back and forth for approximately 10 seconds in a horizontal motion on a flat surface** in order to sufficiently wet the nystatin powder.

3. Next, vigorously shake the suspension bottle in a **vertical motion for at least 60 seconds**.

4. Tap the top and bottom of the lidocaine hydrochloride bottle. Open the suspension bottle and empty the lidocaine hydrochloride powder into the suspension. Close the suspension bottle again and vigorously shake it vertically for approximately 30 seconds.

5. Likewise, tap the top and bottom of the diphenhydramine hydrochloride powder bottle. Remove the cap and because of the hygroscopic nature and small volume of the powder, using the enclosed spatula, empty the contents of the small bottle containing diphenhydramine hydrochloride into the mouthwash suspension. Close the suspension bottle again and vigorously shake it vertically for approximately 30 seconds.

The appropriate quantities of nystatin, lidocaine hydrochloride, and diphenhydramine hydrochloride powders have been packaged in each bottle to deliver the required dosage of each drug. Residual powder remaining in the bottles after emptying need not be rinsed out.

Prior to compounding, store FIR<sub>ST</sub><sup>®</sup>- BXN Mouthwash Compounding Kit at room temperature not to exceed 25°C (77°F). Store final compounded formulation at refrigerated temperature, 2°-8°C (36°-46°F) [see USP].

FIR<sub>ST</sub><sup>®</sup>- BXN Mouthwash Compounding Kit components have a two-year expiration date.\*\*\* Based on real time refrigerated temperature testing, *compounded* FIR<sub>ST</sub><sup>®</sup>- BXN Mouthwash Compounding product is stable for at least thirty days.\*\*\*

FIR<sub>ST</sub><sup>®</sup>-Mouthwash Suspension II 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 ssp.* when tested as described in the current USP under <61> Microbial Enumeration Tests and <62> Tests for Specified Microorganisms. FIR<sub>ST</sub><sup>®</sup>- Mouthwash Suspension II also meets the requirements as described in the current USP under <51> Antimicrobial Effectiveness Testing for Category 2 and Category 3 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 30 days at refrigerated temperature.***

\* Certificate of analysis on file

\*\* This product is not manufactured by Pfizer, Inc., manufacturer of Benadryl<sup>®</sup> or by AstraZeneca LP, manufacturer of Xylocaine<sup>®</sup> 2% Viscous.

\*\*\* Data and documentation on file

**R ONLY**

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U.S. Patent Pending

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