LISTERINE NIGHTLY RESET ANTICAVITY FLUORIDE TWILIGHT MINT- sodium fluoride mouthwash
Johnson & Johnson Consumer Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

LISTERINE® Nightly Reset™ Anticavity Fluoride Mouthwash Twilight Mint™

Drug Facts

Active ingredients

Sodium fluoride 0.02% (0.01% w/v fluoride ion)

Purpose

Anticavity

Uses

Aids in the prevention of dental cavities

Warnings

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 12 years of age and older:
  - use twice a day after brushing your teeth with a toothpaste
  - vigorously swish 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute and then spit out
  - do not swallow the rinse
  - do not eat or drink for 30 minutes after rinsing
  - supervise children as necessary until capable of using without supervision
- Children under 12 years of age: consult a dentist or doctor

Other information

- store at room temperature
- cold weather may temporarily cloud this product

Inactive ingredients

water, sorbitol, propylene glycol, xylitol, poloxamer 407, sodium lauryl sulfate, sodium benzoate, phosphoric acid, eucalyptol, flavor, methyl salicylate, thymol, sodium saccharin, menthol, sucralose, disodium phosphate, red 40, blue 1

Questions?

call toll-free **888-222-0182** or **215-273-8755** (collect). www.listerine.com

Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 800 mL Bottle Label

ANTICAVITY FLUORIDE MOUTHWASH

Sodium Fluoride & Acidulated Phosphate Topical Solution

LISTERINE®

NEW!

NIGHTLY
RESET™

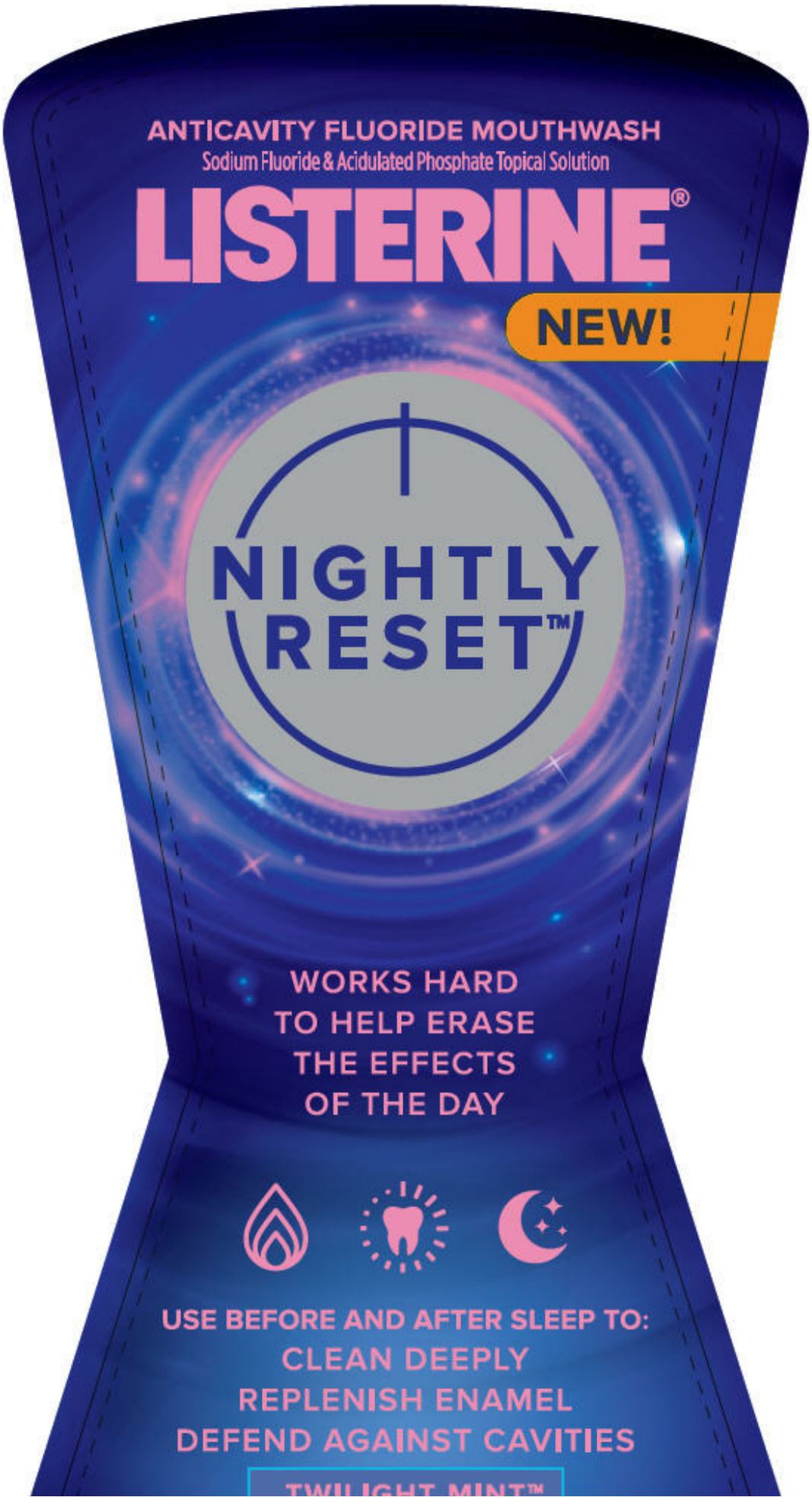
WORKS HARD
TO HELP ERASE
THE EFFECTS
OF THE DAY

USE BEFORE AND AFTER SLEEP TO:
CLEAN DEEPLY
REPLENISH ENAMEL
DEFEND AGAINST CAVITIES

TWILIGHT MINT™
LESS INTENSE

IMPORTANT:
READ DIRECTIONS
FOR PROPER USE.

800 mL(1.7 pt)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Sodium Fluoride & Acidulated Phosphate Topical Solution
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Normal eating and drinking can expose your teeth to sugar acids throughout the day that can leave you vulnerable to cavities – especially overnight. Nightly Reset™ can help reverse the effects of the day by providing a deeper clean than brushing alone and helping to prevent cavities. LISTERINE® Nightly Reset™ is unique because it's specially formulated with a less intense, zero alcohol Twilight Mint™ flavor that's perfect for bedtime. Use before and after sleep as part of a regular routine.

Drug Facts

Active ingredient — **Purpose**

Sodium fluoride 0.02% (0.01% w/v fluoride ion) ..... Anticavity

Use aids in the prevention of dental cavities

Warnings

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Directions

- Adults and children 12 years of age and older:
  - use twice a day after brushing your teeth with a toothpaste
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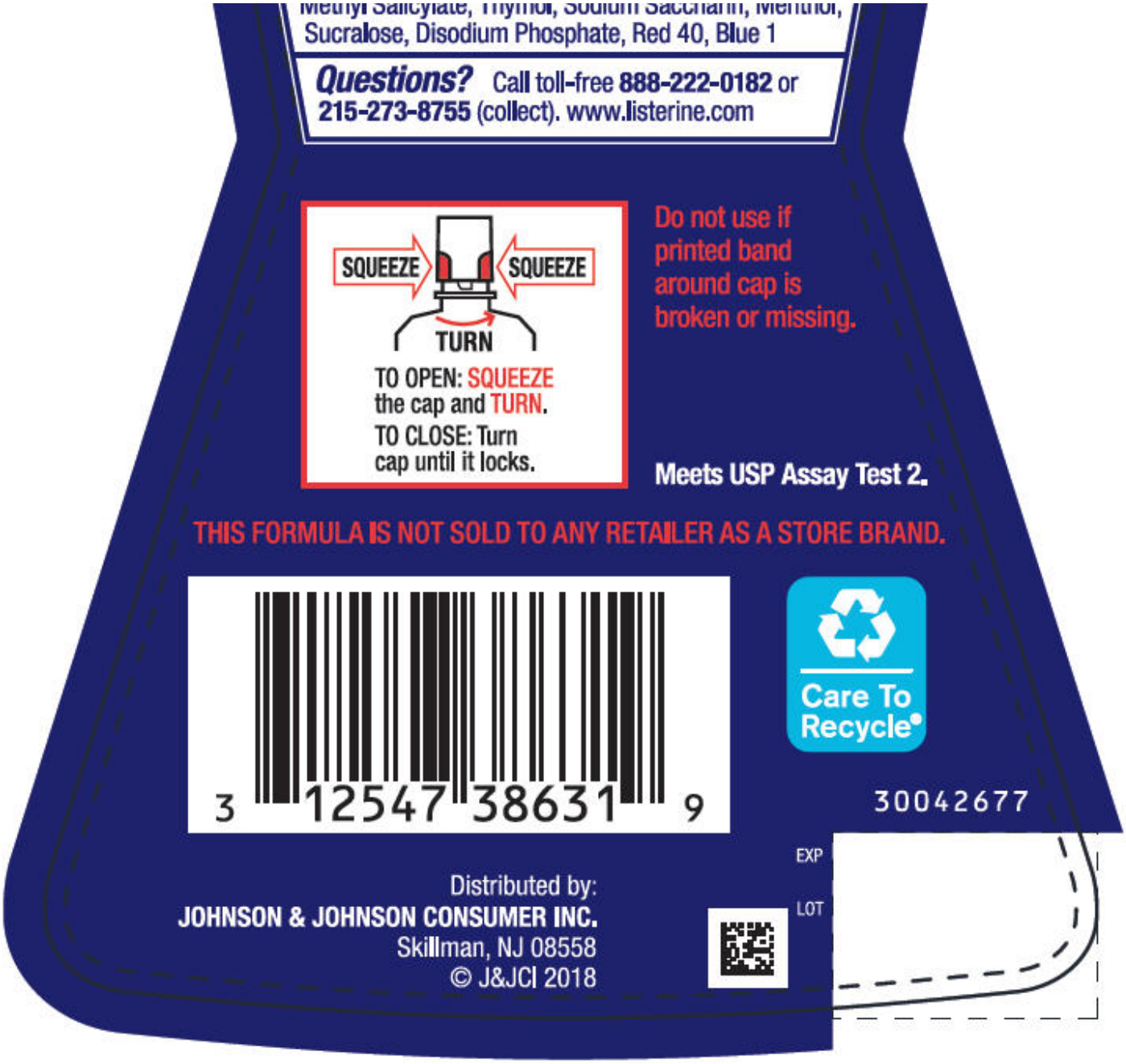
Other information

- store at room temperature
- cold weather may temporarily cloud this product

Inactive ingredients Water, Sorbitol, Propylene Glycol, Xylitol, Poloxamer 407, Sodium Lauryl Sulfate, Sodium Benzoate, Phosphoric Acid, Eucalyptol, Flavor, Methyl Salicylate, Thymol, Sodium Saccharin, Menthol



LISTERINE NIGHTLY RESET ANTICAVITY FLUORIDE TWILIGHT MINT

sodium fluoride mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69968-0478
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Sodium Fluoride	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
Sorbitol (UNII: 506T60A25R)	
xylitol (UNII: VCQ006KQ1E)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Phosphoric Acid (UNII: E4GA8884NN)	
Eucalyptol (UNII: RV6J6604TK)	
Thymol (UNII: 3J50XA376E)	
Methyl Salicylate (UNII: LAV5U5022Y)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Menthol, Unspecified Form (UNII: L7T10EIP3A)	
Sodium Phosphate, Dibasic, Anhydrous (UNII: 22ADO53M6F)	
Sucralose (UNII: 96K6UQ3ZD4)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69968-0478-8	800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2018	
2	NDC:69968-0478-4	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	06/01/2018	

Labeler - Johnson & Johnson Consumer Inc. (002347102)

Revised: 5/2020 Johnson & Johnson Consumer Inc.