LISTERINE TOTAL CARE ZERO ALCOHOL ANTICAVITY FRESH 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 ® TOTAL CARE ZERO ALCOHOL ANTICAVITY MOUTHWASH FRESH MINT

Drug Facts

Active ingredient

Sodium Fluoride 0.02% (0.01% w/v Fluoride Ion)

Purpose

Anticavity

Use

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 6 years of age and older:
 - use twice daily after brushing your teeth with a toothpaste
 - vigorously swish 10mL (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
 - instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
 - o supervise children as necessary until capable of using without supervision
- Children under 6 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, Poloxamer 407, Sodium Lauryl Sulfate, Flavor, Sodium Benzoate, Phosphoric Acid, Eucalyptol, Methyl Salicylate, Thymol, Sodium Saccharin, Menthol, Disodium Phosphate, Sucralose, Red 40, Blue 1

Questions?

call toll-free 888-222-0182 or 215-273-8755 (collect)

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

PRINCIPAL DISPLAY PANEL - 1000 mL Bottle Label
ANTICAVITY FLUORIDE MOUTHWASH

LISTERINE®

TOTAL CARE

IMPORTANT: READ DIRECTIONS FOR PROPER USE
SODIUM FLUORIDE & ACIDULATED PHOSPAHTE TOPICAL SOLUTION
ZERO ALCOHOL

6 IN 1

BENEFITS

- 1. 24-HOUR CAVITY PROTECTION+
- 2. **RESTORES ENAMEL**
- 3. STRENGTHENS TEETH
- 4. FRESHENS BREATH
- 5. CLEANS WHOLE MOUTH
- 6. KILLS BAD BREATH GERMS

+when used twice daily *bad breath germs

1.0L (1 Qt 1.8 Fl Oz)

FRESH MINT

24-HR CAVITY PROTECTION[†]
& KILLS 99.9% OF GERMS^{*}
WITH A LESS INTENSE TASTE





LISTERINE TOTAL CARE ZERO ALCOHOL ANTICAVITY FRESH MINT

sodium fluoride mouthwash

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0194	
Route of Administration	ORAL			

Active Ingredient/Active Moiety

Ingredient Name

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION

0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name
Strength

WATER (UNII: 059QF0KO0R)

SORBITOL (UNII: 506T60A25R)

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)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:69968- 0194-2	27 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/25/2012			
2	NDC:69968- 0194-9	95 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/25/2012			
3	NDC:69968- 0194-5	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/25/2012			
4	NDC:69968- 0194-1	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/25/2012			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part355	07/25/2012			

Labeler - Johnson & Johnson Consumer Inc. (118772437)

Revised: 1/2023 Johnson & Johnson Consumer Inc.