LISTERINE HEALTHY WHITE RESTORING ANTICAVITY FLUORIDE CLEAN 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® HEALTHY WHITE® RESTORING ANTICAVITY FLUORIDE MOUTHWASH CLEAN MINT

Drug Facts

Active ingredient

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

Purpose

Anticavity

Use

aids in prevention of dental cavities

Warnings

Stop use and ask dentist if oral irritation or tooth sensitivity occurs

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

• Protect from excessive heat (40°C/104°F)

Inactive ingredients

Water, alcohol (10.5% v/v), sorbitol, hydrogen peroxide, PEG-40 hydrogenated castor oil, poloxamer 407, sodium saccharin, menthol, flavor, phosphoric acid, disodium phosphate, sucralose

Questions?

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

Distributed by: JOHNSON & JOHNSON CONSUMER INC.

Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 946 mL Bottle Label

ANTICAVITY FLUORIDE MOUTHWASH

LISTERINE®

HEALTHY WHITE®

RESTORING

SODIUM FLUORIDE &

ACIDULATED PHOSPHATE TOPICAL SOLUTION

IMPORTANT: READ DIRECTIONS FOR PROPER USE

FOR A HEALTHIER

MOUTH

*vs brushing alone

in a lab study

CLEAN MINT

946mL (32 Fl Oz)



30042129



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FOR A HEALTHIER **MOUTH**

30042125

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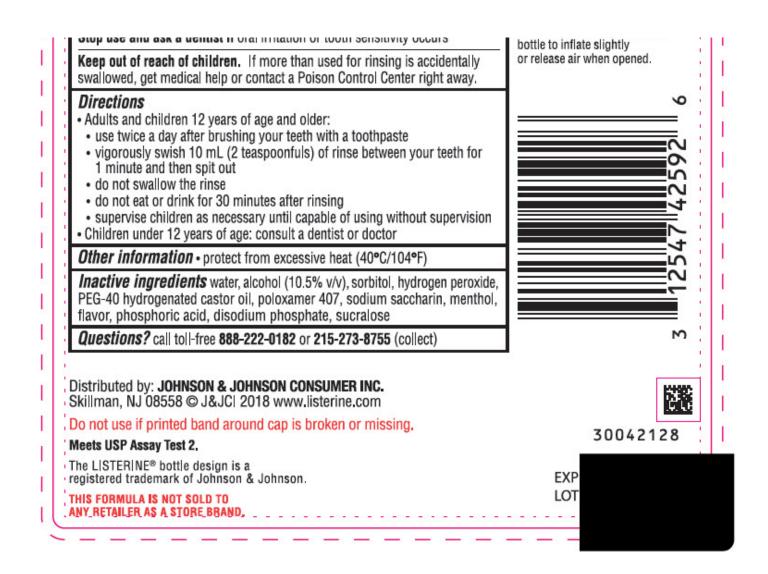
Warnings

Ston use and ask a dentist if oral irritation or tooth consitivity occurs



TO OPEN: SQUEEZE SQUEEZE the cap and TURN. TO CLOSE: Turn cap until it locks.

Contains Active Dental Peroxide which releases oxygen while whitening. This may cause the



LISTERINE HEALTHY WHITE RESTORING ANTICAVITY FLUORIDE CLEAN MINT

sodium fluoride mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0500
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)		
Alcohol (UNII: 3K9958V90M)		
Sorbitol (UNII: 506T60A25R)		
Hydrogen Peroxide (UNII: BBX060AN9V)		

POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
Phosphoric Acid (UNII: E4GA8884NN)	
Sucralose (UNII: 96K6UQ3ZD4)	
SO DIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10 EIP3A)	

	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:69968-0500-1	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/20 10	
:	NDC:69968-0500-2	946 mL in $1BOTTLE;$ Type $0\colon Nota$ Combination Product	0 1/0 1/20 10	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	0 1/0 1/20 10	

Labeler - Johnson & Johnson Consumer Inc. (002347102)

Revised: 5/2020 Johnson & Johnson Consumer Inc.