ANTICAVITY- sodium fluoride mouthwash Big Lots

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.

Anticavity Fluoride Rinse 163.005/163AF

Active ingredient

Sodium fluoride 0.0221% (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 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute then spit out
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- instruct children uder 12 years of age in good rinsing habits (to minimize swallowing)
- 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 controlled room temperature 20°-25° C to (68° 77°F)
- cold weather may temporarily cloud this product

Inactive ingredients

water, alcohol (21.6 %v/v), sorbitol, poloxamer 407, eucalyptol, flavor, methyl salicylate, menthol, phosphoric acid, sodium saccharin, thymol, disodium phosphate, sucralose, red 40, blue 1

Questions

Call 1-888-593-0593

Sealed with printed neckband for your protection.

Do not use if band around cap is broken or missing.

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine Total Care Fresh Mint Anticavity Mouthwash

Manufactured for Big Lots by Vi-Jon, Inc 8515 Page Avene St. Louis, MO 63114

principal display panel

SOUND BODY

COMPARE TO LISTERINE TOTAL CARE ANTICAVITY MOUTHWASH

ANTICAVITY FLUORIDE RINSE

Sodium Fluoride and Acidulated Phosphate Topical Solution

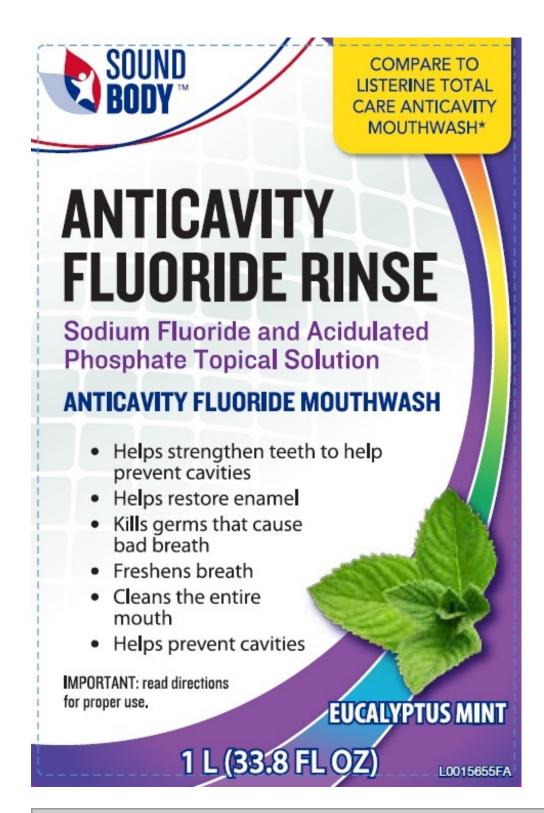
ANTICAVITY FLUORIDE MOUTHWASH

- Helps strengthen teeth to help prevent cavities
- Helps restore enamel
- Kills germs that cause bad breath
- Freshens breath
- Cleans the entire mouth
- Helps prevent cavities

IMPORTANT: read directions for proper use

EUCALYPTUS MINT

1L (33.8 FL OZ)



ANTICAVITY

sodium fluoride mouthwash

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50594-163

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	0.1 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ALCOHOL (UNII: 3K9958V90M)		
SORBITOL (UNII: 506T60A25R)		
POLOXAMER 407 (UNII: TUF2IVW3M2)		
EUCALYPTOL (UNII: RV6J6604TK)		
METHYL SALICYLATE (UNII: LAV5U5022Y)		
MENTHOL (UNII: L7T10EIP3A)		
PHO SPHO RAMIDIC ACID (UNII: 9Q189608GB)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
THYMOL (UNII: 3J50 XA376E)		
SO DIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)		
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
	NDC:50594-163- 86	$1000\ mL$ in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/17/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	03/17/2016	

Labeler - Big Lots (017885351)

Registrant - Vi Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture(50594-163)

Revised: 4/2020 Big Lots