

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 under 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 Avenue 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)



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L0015655FA

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:Q80VPU408O)		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)				
PHOSPHORAMIDIC ACID (UNII: 9Q189608GB)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
THYMOL (UNII: 3J50XA376E)				
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (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
1	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