ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash CVS Pharmacy, 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.

Drug Facts CVS 163.005/163AF-AG

Active Ingredient

Sodium fluoride 0.0221% (0.01% fluoride ion)

Purpose

Antcavity

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 and then spit it 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

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

Other information

- store at controlled room temperature 20° 25° C (68° 77° F)
- cold weather may temporarily cloud this product

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

Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 2017 CVS/pharmacy www.cvs.com 1-800-shop-CVS

principal display panel

CVS Health

Compare to the active ingredient in Listerine Total Care Anticavity Mouthwash

Anticavity Fluoride Mouthwash

SODIUM FLUORIDE

6 Benefits:

- Restores enamel
- Helps prevent cavities
- Cleans entire mouth
- Kills bad breath germs
- Strengthens teeth
- Freshens breath

Eucalyptus Mint

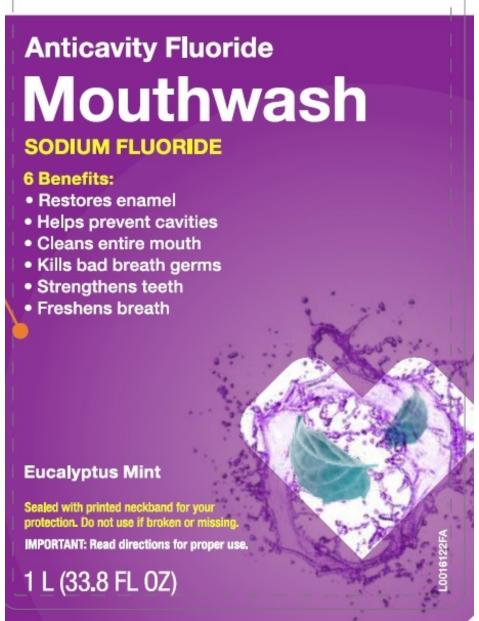
Sealed with printed neckband for your protection. Do not use if broken or missing.

IMPORTANT: Read directions for proper use.

1 L (33.8 FL OZ)



Compare to the active ingredient in Listerine® Total | Care Anticavity Mouthwash*



ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:59779-163

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

Inactive Ingredients		
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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)		
PHOSPHORIC ACID (UNII: E4GA8884NN)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
THYMOL (UNII: 3J50XA376E)		
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:59779- 163-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2008		
2	NDC:59779- 163-86	1000 mL in 1 PACKAGE; Type 0: Not a Combination Product	09/15/2008		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	09/15/2008		

Labeler - CVS Pharmacy, Inc (062312574)

Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(59779-163)	

Revised: 9/2023 CVS Pharmacy, Inc