ANTICAVITY- sodium fluoride rinse 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.

Anticavity Fluoride Rinse, Mint 213.002/213AE rev 2

Active ingredient

Sodium Fluoride 0.05% (0.02% w/v fluoride ion)

Purpose

Anticavity rinse

Use

aids in the prevention of dental cavities

Warning

for this product

Keep out of reach of children

If more than used for rinsing is accidentally swallowed, seek professional assistance or contact a Poison Control Center immediately.

Directions

- adults and children 6 years of age and older: use once a day after brushing your teeth with toothpaste
- remove cap
- pour 10 milliliters (10 ML mark on the inside of cap); do not fill above 10 ML mark
- vigorously swish 10 millilters 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)
- 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

Inactive ingredients

water, sorbitol, menthol, methyl salicylate, flavor, cetylpyridinium chloride, sodium saccharin, poloxamer 407, polysorbate 20, propylene glycol, sodium phosphate, disodium phosphate, calcium disodium EDTA, disodium EDTA, sodium benzoate, potassium sorbate, benzyl alcohol, green 3, yellow 5

*This product is not manufactured or distributed by Chattem, Inc., distributor of ACT Anticavity Fluoride Mouthwash.

Distributed by:

CVS Pharmacy, Inc

One CVS Drive

Woosocket, RI 02895

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CVS.com

1-800-SHOP CVS

CVS Quality

Money Back Guarantee

PLEASE RECYCLE

Principal display panel

CVS HEALTH

Compare to the active ingredient in ACT Anticavity Fluoride Mouthwash*

Anticavity Fluoride Rinse

ALCOHOL FREE

- Helps prevent tooth decay
- Strengthens teeth
- Strong cavity protection
- Freshens breath

Mint Flavor

ADA Accepted

American Dental Association

Helps prevent cavities

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

IMPORTANT: Read Directions for proper use.



Compare to the active ingredient in ACT® Anticavity Fluoride Mouthwash*



ANTICAVITY

sodium fluoride rinse

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:59779-213

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

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

0.2 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
water (UNII: 059QF0KO0R)				
sorbitol (UNII: 506T60A25R)				
MENTHOL (UNII: L7T10EIP3A)				

METHYL SALICYLATE (UNII: LAV5U5022Y)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

ı	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:59779-213-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2001		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	06/19/2001		

Labeler - CVS Pharmacy, Inc. (062312574)

Registrant - Vi Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi Jon, LLC		790752542	manufacture(59779-213)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi Jon, LLC		088520668	manufacture(59779-213)	

Revised: 5/2023 CVS Pharmacy, Inc.