

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 Rinse
213

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 milliliters 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

ADA Statement

"The ADA Council on Scientific Affairs Acceptance of CVS Health Anticavity Fluoride Rinse is based on its finding that the product is effective in helping to prevent and reduce tooth decay, when used as directed."

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

Distributed by:

CVS Pharmacy, Inc

One CVS Drive

Woosocket, RI 02895

1-800-SHOP CVS

213.002213AE rev 2

Principal Display Panel

CVS HEALTH

Compare to the active ingredient in ACT Anticavity Fluoride Rinse

Anticavity Fluoride Rinse

ALCOHOL FREE

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

Mint Flavor

ADA Accepted

American Dental Association

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

IMPORTANT: Read Directions for proper use.

18 FL OZ (532 mL)



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L0010786FB

ANTICAVITY

sodium fluoride rinse

Product Information

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:Q80VPU408O)	FLUORIDE ION	0.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
sorbitol (UNII: 506T60A25R)	
MENTHOL (UNII: L7T10EP3A)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
CETYL PYRIDINIUM 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)	

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 (790752542)

Establishment

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