ANTICAVITY- sodium fluoride rinse Shopko Stores Operating Co., LLC

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 Ingredients

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, see 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 a toothpaste
- remove cap
- pour 10 milliliters (10 mL mark on the inside of cap); do not fill above the 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 minimixe 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

Disclaimer

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

Adverse reactions

Manufactured by Vi-Jon, Inc.,

One Swan Drive, Smyrna, TN 37167

for Shopko Stores Operating Co., LLC

www.shopko.com

for consumer questions

call 1-888-593-0593

SHOPKO

Satisfaction

Guaranteed by refund or exchange

Principal display panel

SHOPKO

COMPARE TO THE ACTIVE INGREDIENT OF ACT

Anticavity

Fluoride

Rinse

Mint Flavor

Strong cavity protection

Helps strengthen teeth

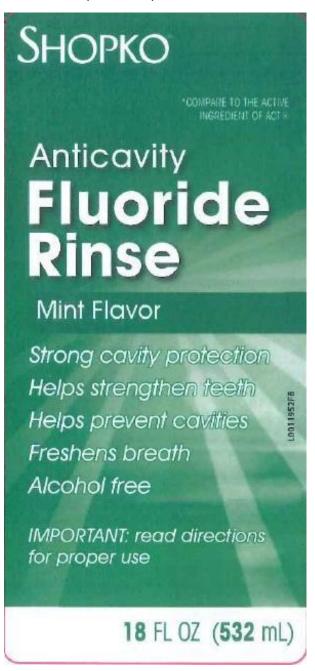
Helps prevent cavities

Freshens breath

Alcohol Free

IMPORTANT: read directions for proper use

18 FL OZ (532 mL)



ANTICAVITY sodium fluoride rinse Product Information Product Type HUMAN OTC DRUG Item Code (Source) 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: 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 (UNII: SE337SVY37)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)	
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	
	NDC:37012- 213-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/02/2011	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/02/2011	

Labeler - Shopko Stores Operating Co., LLC (023252638)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(37012-213)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(37012-213)

Revised: 5/2023

Shopko Stores Operating Co., LLC