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, Bubble Gum 004.001/004E

Active ingredient

Sodium fluoride 0.055% (0.02% w/v fluoride ion)

Purpose

Anticavity rinse

Use

aids in the prevention of dental cavities

Warnings

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 mililiters (10 mL mark on inside of cap); do not fill above thr 10 mL mark
- vigorously swish 10 mililiters 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

benzyl alcohol, calcium disodium EDTA, cetylpridinium chloride, disodium EDTA, disodium phosphate, flavor, poloxamer 407, polysorbate 80, propylene glycol, red 33, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water

Sealed with printed neckband for your protection.

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

Manufactured by Vi-Jon, LLC.,

One Swan Dr., Smyrna, TN 37167

for ShopKo Stores Operating Co., LLC

www.shopko.com

For consumer questions call 1-888-593-05936

ShopKo Satisfaction Guaranteed By Refund Or Exchange

principal display panel

ShopKo

Compare to the Active Ingredient of Act*

Kids Anticavity Fluoride Rinse

Bubble Gum Flavor

Strong cavity protection

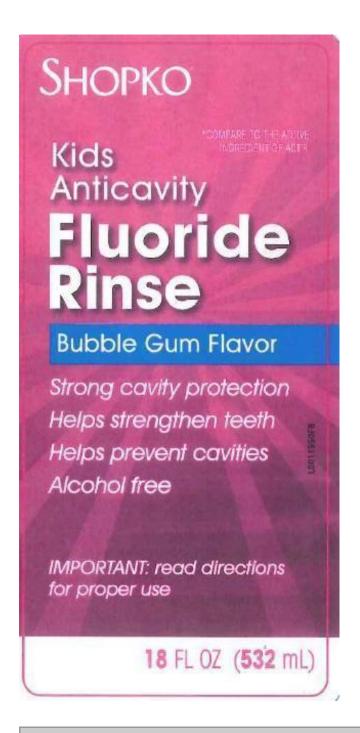
Helps strengthen teeth mm1.jpg

Helps prevent cavities

Alcohol Free

IMPORTANT: read directions for proper use

18 FL OZ (532 mL)



ANTICAVITY

sodium fluoride rinse

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-004
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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		
BENZYL ALCOHOL (UNII: LKG8494WBH)			
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)			
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
POLYSORBATE 80 (UNII: 60ZP39ZG8H)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
D&C RED NO. 33 (UNII: 9DBA0SBB0L)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SODIUM PHOSPHATE (UNII: SE337SVY37)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SORBITOL (UNII: 506T60A25R)			
WATER (UNII: 059QF0KO0R)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:37012- 004-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2011	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/15/2011	

Labeler - Shopko Stores Operating Co.LLC (023252638)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(37012-004)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(37012-004)