

ALCOHOL-FREE ANTICAVITY- sodium fluoride liquid
ShopKo Stores Operating., 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
482

Active ingredient

Sodium fluoride 0.02% (0.01% w/v fluoride ion)

Purpose

Anticavity

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 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

Inactive ingredients

water, glycerin, cetylpyridinium chloride, flavor, sodium saccharin, phosphoric acid, sodium benzoate, sucralose, poloxamer 407, benzoic acid, disodium phosphate, propylene glycol, red 33, green 3

Sealed with printed neckband for your protection

To Open:

1. Remove Printed Tamper Evident Neckband
2. Squeeze Both tabs at Base of cap While turning the cap until loose.

To Close: Place cap back on bottle and turn cap until it clicks twice and feels secure.

This rinse may cause temporary staining to the surface of teeth. This is not harmful, and adequate brushing may prevent its occurrence.

*This product is not manufactured or distributed by Procter & Gamble, distributor of Crest Pro-Health Complete Anticavity Fluoride Rinse

Manufactured by Vi-Jon, Inc

One Swan Dr., Smyrna, TN 37167

for ShopKo Stores Operating Co., LLC

www.shopko.com

for consumer questions

call 1-888-593-0593

principal display panel

ShopKo

Compare to the active ingredient of Crest*

Alcohol Free

ANTICAVITY FLUORIDE RINSE

Violet Mint

Kills bad breath germs

Helps prevent cavities

Helps strengthen enamel

Cleans teeth

Freshens breath

IMPORTANT: read directions for proper use.

33.8 FL OZ (1 L)

SHOPKO®

*COMPARE TO THE ACTIVE
INGREDIENT OF CREST®

Alcohol Free
**Anticavity
Fluoride
Rinse**

L0012797FB

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Cleans teeth
Freshens breath*

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33.8 FL OZ (1 Liter)

ALCOHOL-FREE ANTICAVITY

sodium fluoride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-482
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POLOXAMER 407 (UNII: TUF2IWW3M2)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012-482-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1982	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/15/1982	

Labeler - ShopKo Stores Operating., LLC (023252638)**Registrant** - Vi-Jon, LLC (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(37012-482)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(37012-482)

