

ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash
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 163

Active ingredients

Sodium fluoride 0.0221% (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 12 years of age and older:

- use twice daily after brushing your teeth with toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) 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
- supervise children as necessary until capable of using without supervision
- children under 12 years of age: consult a dentist or doctor

Other information

- store at controlled room temperature 20° -25° C (68° - 77° F)
- cold weather may temporarily cloud this product

Inactive ingredients

water, sorbitol solution, alcohol (21.8%), flavors, poloxamer 407, sodium lauryl sulfate, phosphoric acid, sucralose, dibasic sodium phosphate, FD+C yellow no.6, FD+C red no. 40, FD+C blue no. 1

adverse reaction

Sealed with printed neckband for your protection

*This product is not manufactured or distributed by Johnson + Johnson Healthcare Products, distributor of Listerine Total Care Anticavity Mouthwash

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
SHOPKO Satisfaction Guaranteed By Refund Or Exchange

principal display panel

SHOPKO

Anticavity FLUORIDE RISE

Sodium Fluoride and Acidulated Phosphate Topical Solution

Eucalyptus Mint

Helps prevent cavities

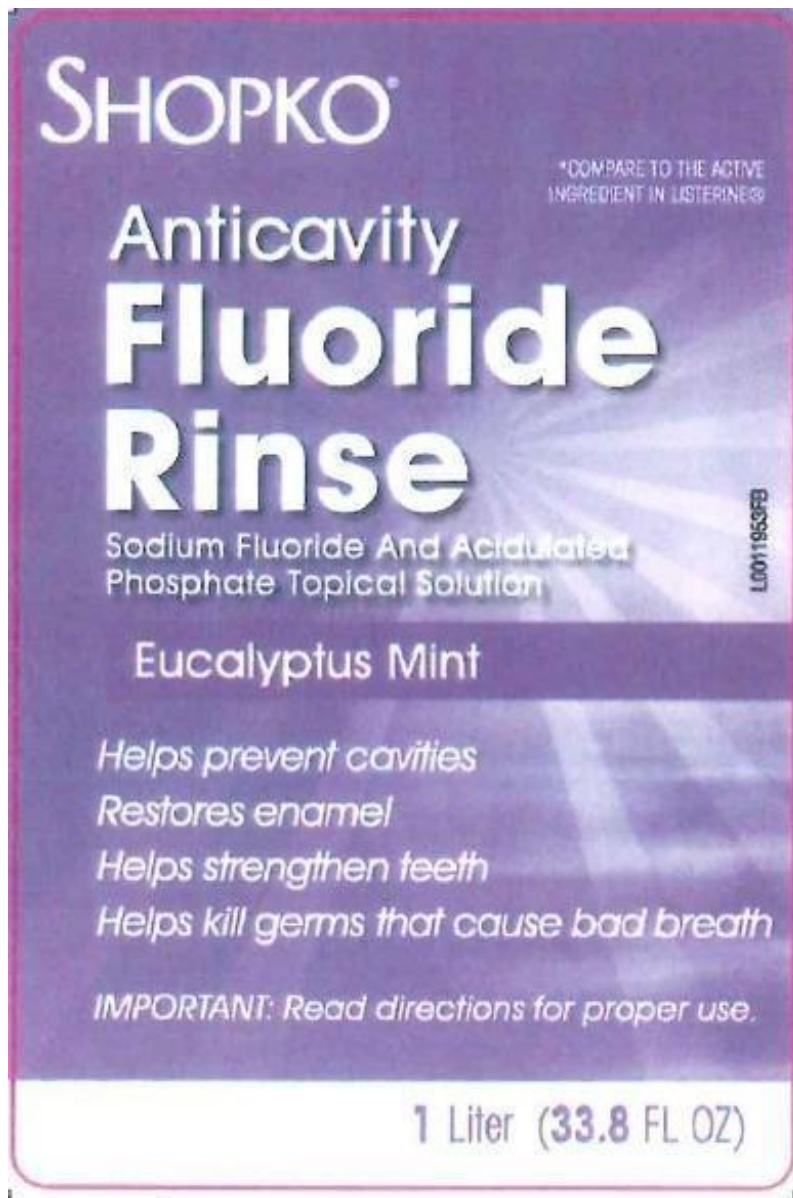
Restores enamel

Helps strengthen teeth

Helps kill germs that cause bad breath

IMPORTANT: Read directions for proper use.

1 Liter (33.8 FL OZ)



ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:370 12-163
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)	

SORBITOL (UNII: 506T60A25R)	
ALCOHOL (UNII: 3K9958V90M)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
sucralose (UNII: 96K6UQ3ZD4)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:370 12-163-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/13/2006	

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

Registrant - Vi Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture(370 12-163)