

ANTICAVITY- sodium fluoride liquid
ShopKo

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.

Shopko 435.000 435AA

Active ingredient

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

purpose

Anticavity

Use

aids in the prevention of dental cavities

Warnings

For this product

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 a day after brushing your teeth with 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, alcohol (8%), hydrogen peroxide, poloxamer 407, sodium saccharin, sucralose,

menthol, phosphoric acid, disodium phosphate, flavor

Other information

- store at room temperature (59° - 77° F)

Disclaimer

This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine HealthyWhite Anticavity Mouthrinse

Other safety information

Contains peroxide which releases oxygen while whitening. This may cause the bottle to inflate slightly or release air when opened.

Adverse Reactions

Manufactured by:

Vi-Jon, LLC 1 Swan Drive

Smyrna, TN 37167

Shopko Store Operating Co, LLC

www.shopko.com

For consumer questions

call 1-888-593-0593

Satisfaction

SHOPKO

Guaranteed

principal display panel

ShopKo

NDC 37012-435-43

COMPARE TO THE

INGREDIENTS OF LISTERINE

Glowing

White

Anticavity Mouthrinse

Fresh Mint

Begins working on contact

5 days to whiter teeth

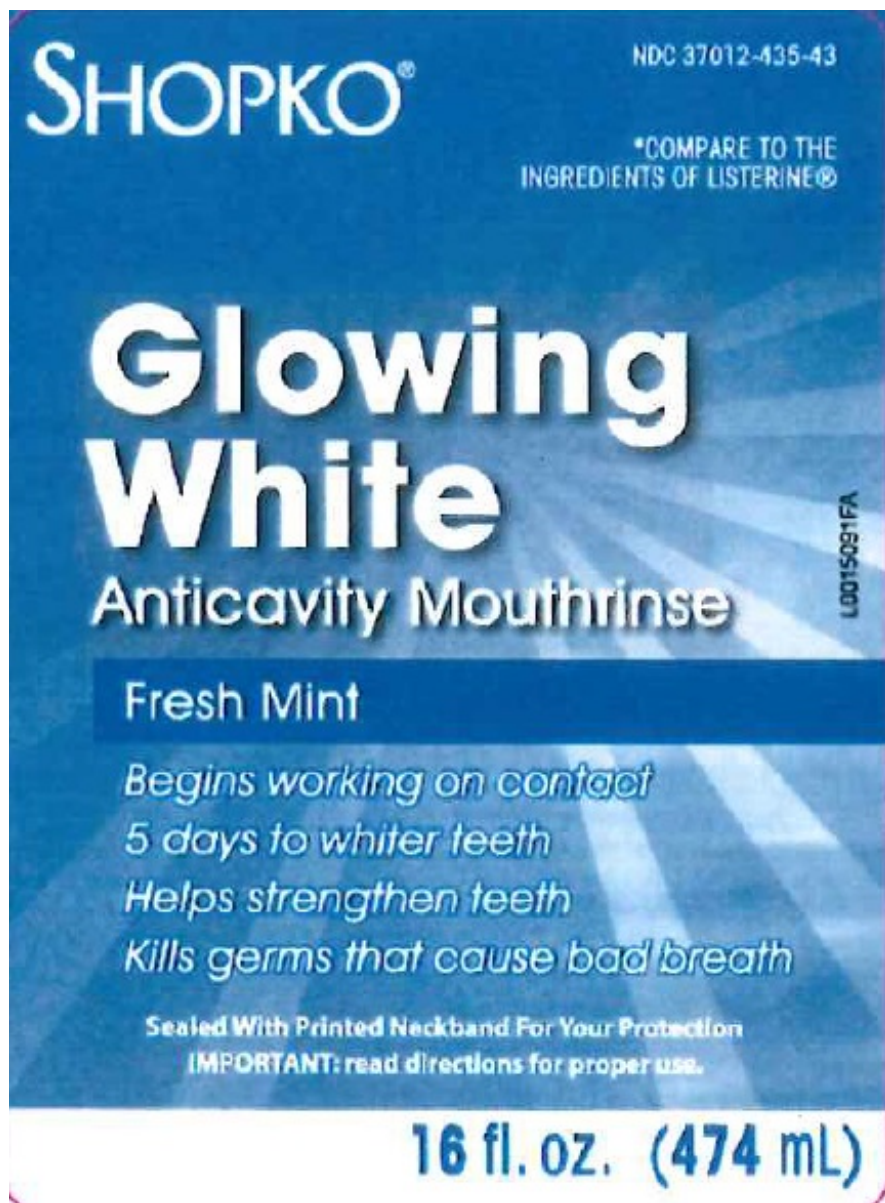
Helps strengthen teeth

Kills germs that cause bad breath

Sealed With Printed Neckband For Your Protection

IMPORTANT: read directions for proper use.

16 fl oz (474 mL)



ANTICAVITY

sodium fluoride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-435
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)	
ALCOHOL (UNII: 3K9958V90M)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
POLOXAMER 407 (UNII: TUF2IWW3M2)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MENTHOL (UNII: L7T10EIP3A)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012-435-43	474 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	04/01/2015	

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

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(37012-435)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(37012-435)