

ANTICAVITY- sodium fluoride mouthwash DZA Brands

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.

Healthy Accents 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 a 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
- 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 Vibrant Anticavity Mouthrinse

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

Adverse Reactions

DISTRIBUTED BY: DZA BRANDSA, LLC

2110 Executive Drive, Salisbury, NC 28147

For product questions or concerns, contact us at 1-866-322-2439

Please include UPC number and code from package

principal display panel

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

IMPORTANT: READ DIRECTIONS FOR PROPER USE.

healthy

accents

glowing white

anticavity

mouth rinse

fresh mint

- begins working on contact
- 5 days to whiter teeth
- helps strengthen teeth
- kills germs that cause bad breath

compare to Listerine Healthy White

Vibrant Anticavity Mouthrinse

32 FL OZ (1 QT) 946 mL

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compare to Listerine® HealthyWhite™
Vibrant Anticavity Mouthrinse*

32 FL OZ (1 QT) 946mL

L0015080FA

ANTICAVITY

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55316-435
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: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
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:55316-435-45	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/11/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/11/2015	

Labeler - DZA Brands (090322194)**Registrant** - Vi-Jon, LLC (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55316-435)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55316-435)