

**ANTICAVITY- sodium fluoride mouthwash**  
**RETAIL BUSINESS SERVICES, 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.*

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**Care One 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:

FOODHOLD U.S.A., LLC

LANDOVER, MD 20785

S & S brands, LLC

1-887846-8484

Quality Guaranteed or your money back

## **principal display panel**

CAREONE

Compare to Listerine HealthyWhite Vibrant Anticavity Mouthrinse

ADVANCED

WHITENING

ANTICAVIRY MOUTHRINSE

5 DAYS TO WHITER TEETH

BEGINS WORKING ON CONTACT

SAFELY WHITENS TEETH

KILLS GERMS THAT CAUSE BAD BREATH

FRESH MINT FLAVOR

Sealed With Printed Neckband For Your Protection

IMPORTANT: Read directions for proper use.

16 FL OZ (1 PT) 473 mL

CAREone®

Compare to Listerine®  
HealthyWhite™ Vibrant  
Anticavity Mouthrinse\*

# ADVANCED WHITENING

## ANTICAVITY MOUTHRINSE

5 DAYS TO WHITER TEETH  
BEGINS WORKING ON CONTACT  
SAFELY WHITENS TEETH  
KILLS GERMS THAT CAUSE BAD BREATH

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L0015061FB

16 FL OZ (1 PT) 473 mL

### ANTICAVITY

sodium fluoride mouthwash

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72476-435
<b>Route of Administration</b>	oral		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.2 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	
<b>POLOXAMER 407</b> (UNII: TUF21VW3M2)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-435-45	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/28/2015	
2	NDC:72476-435-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/28/2015	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/01/2015	

**Labeler** - RETAIL BUSINESS SERVICES, LLC (967989935)

**Registrant** - Vi-Jon, LLC (790752542)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72476-435)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(72476-435)

Revised: 4/2022

RETAIL BUSINESS SERVICES, LLC