

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.

Care One Anticavity Fluoride Mouthrinse 163.005/163AF-AG

Active ingredient

Sodium fluoride 0.02% w/v (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 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
- supervise children as necessary until capable of using without supervision
- children under 12 years of age: consult a dentist or doctor

Inactive ingredients

water, alcohol (21.6 %v/v), sorbitol, poloxamer 407, eucalyptol, flavor, methyl salicylate, menthol, phosphoric acid, sodium saccharin, thymol, disodium phosphate, sucralose, red 40, blue 1

Other information

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

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.

DISTRIBUTED BY:

FOODHOLD U.S.A., LLC

LANDOVER, MD 20785

1-877-846-9949

2013 S&S BRANDS, LLC

Quality guaranteed or your money back

Principal display panel

Compare to the Active Ingredient of Listerine Total Care Fresh Mint Anticavity Mouthwash*

CARE ONE

ANTICAVITY MOUTH WASH

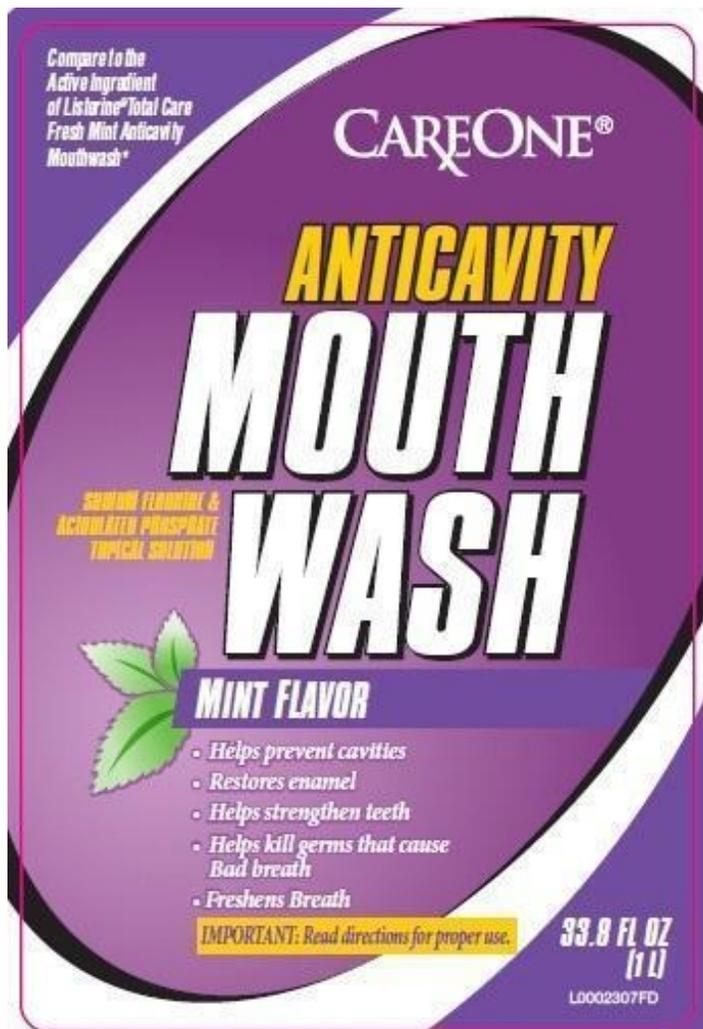
SODIUM FLUORIDE & ACIDULATED PHOSPHATE TOPICAL SOLUTION

MINT FLAVOR

- Helps prevent cavities
- Restores enamel
- Helps strengthen teeth
- Helps kill germs that cause Bad breath
- Freshen Breath

IMPORTANT: Read directions for proper use

33.8 FL OZ (1 L)



ANTICAVITY

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-005
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Alcohol (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
EUCALYPTOL (UNII: RV6J6604TK)	

METHYL SALICYLATE (UNII: LAV5U5022Y)	
MENTHOL (UNII: L7T10EIP3A)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
THYMOL (UNII: 3J50XA376E)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-005-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/12/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/12/2005	

Labeler - RETAIL BUSINESS SERVICES , LLC (967989935)

Registrant - Vi Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		790752542	manufacture(72476-005)