

ANTICAVITY- sodium fluoride mouthwash
Retail Business Services, LLC

Care One 163.004/163AE
Anticavity Fluoride Mouthrinse

Tamper Evident Statement

Sealed With Printed Neckband For Your Protection

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

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 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
- instruct children under 12 of age in good rinsing habits (to minimize swallowing)
- 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° (68° - 77° F)
- cold weather may temporarily cloud this product

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

Disclaimer

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine[®] Total Care Fresh Mint Anticavity Mouthwash.

ADVERSE REACTION

DISTRIBUTED BY:

FOODHOLD U.S.A., LLC

LANDOVER, MD 20785

1-877-846-9949

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Quality guaranteed or your money back

DSP-TN-15000

DSP-MO-34

SDS-TN-15012

Principal display panel

CARE ONE[®]

Compare to Listerine[®] Total Care Fresh Mint Anticavity Mouthwash*

ANTICAVITY

MOUTHWASH

SODIUM FLUORIDE & ACIDULATED PHOSPHATE TOPICAL SOLUTION

Helps prevent cavities and restore enamel

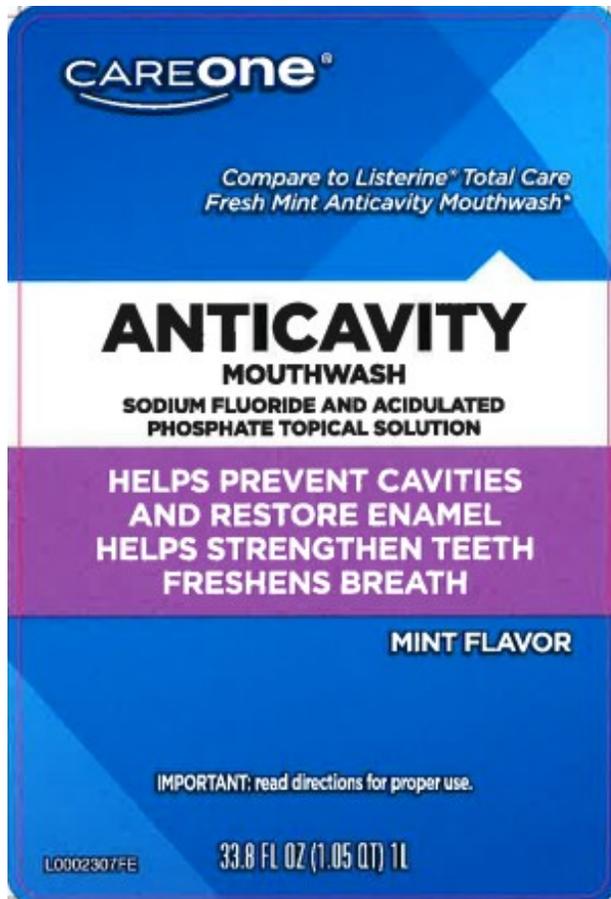
Helps strengthen teeth

Freshens breath

Mint Flavor

IMPORTANT: Read directions for proper use.

33.8 FL OZ (1.05 QT) 1 L



Sealed With Printed Neckband For Your Protection

Drug Facts	
Active ingredient Sodium fluoride 0.02% w/v (0.01% w/v fluoride ion)	Purpose Anticavity
Use aids in the prevention of dental cavities	
Warning 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: <ul style="list-style-type: none"> ■ 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 ■ 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 	
Other information <ul style="list-style-type: none"> ■ store at controlled room temperature 20°-25° C (68°-77° F) ■ cold weather may temporarily cloud this product 	
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DSP-TN-15000
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 SOS-TN-15012

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	0.1 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 Drug	M021	09/12/2005	

Labeler - Retail Business Services, LLC (967989935)

Registrant - Nice-Pak Products, LLC (119091520)

Establishment			
Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(72476-005)