

ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash
Retail Business Services, LLC

Care One 213.002/213AE rev 2
Anticavity Fluoride Rinse, Mint

Active Ingredient

Sodium fluoride 0.05% (0.02% w/v fluoride ion)

Purpose

Anticavity rinse

Use

aids in the prevention of dental cavities

Warning

for this product

Keep out of reach of children.

If more than used for rinsing is accidentally swallowed, seek professional assistance or contact a Poison Control Center immediately.

Directions

- adults and children 6 years of age and older: use once a day after brushing your teeth with a toothpaste
- remove cap
- pour 10 milliliters (10 mL mark on the inside of cap); do not fill above the 10 mL mark
- vigorously swish 10 milliliters 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

Other information

- store at room temperature

Inactive ingredient

water, sorbitol, menthol, methyl salicylate, flavor, cetylpyridinium chloride, sodium saccharin, poloxamer 407, polysorbate 20, propylene glycol, sodium phosphate, disodium phosphate, calcium disodium EDTA, disodium EDTA, sodium benzoate, potassium sorbate, benzyl alcohol, green 3, yellow 5

Disclaimer

*This product is not manufactured or distributed by Chattem, Inc., distributor of Act[®] Anticavity Fluoride Rinse.

ADVERSE REACTION

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CAREONE[®]

Compare to Act[®] Anticavity Fluoride Rinse*

ANTICAVITY

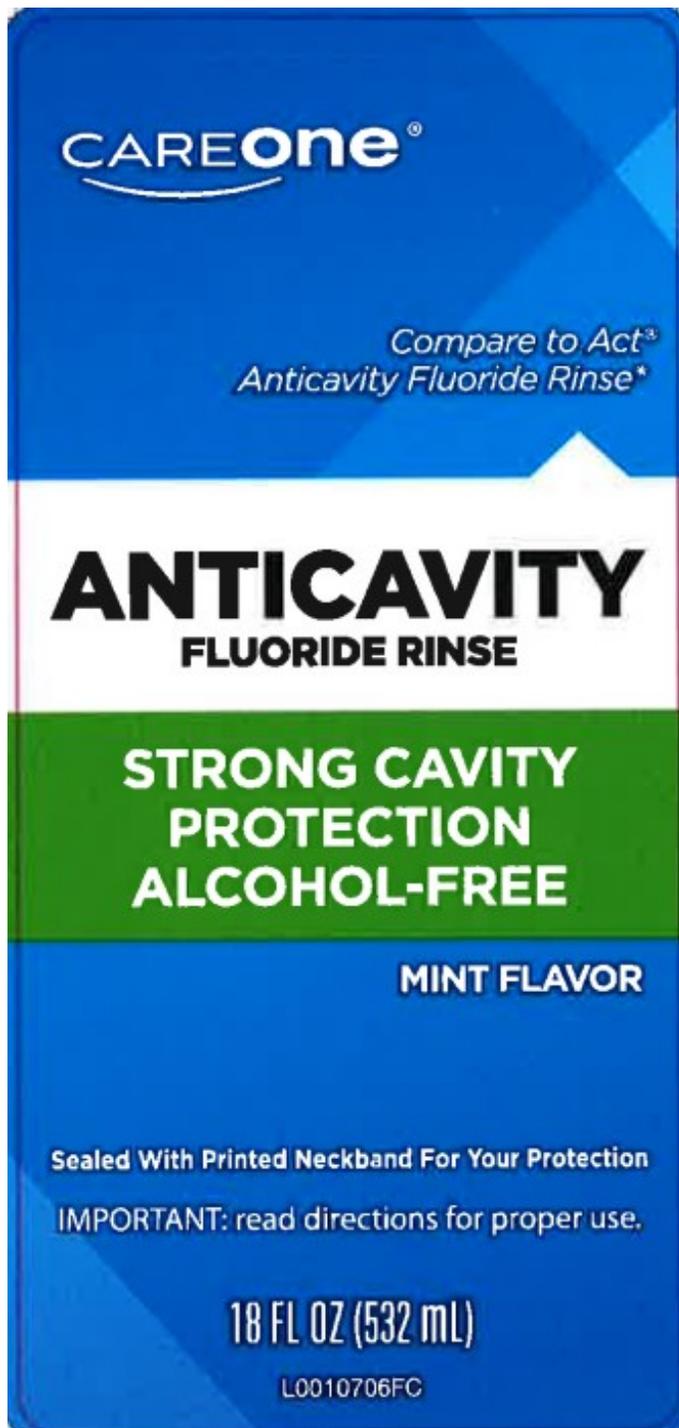
FLUORIDE RINSE

MINT FLAVOR

Sealed With Printed Neckband For Your Protection

IMPORTANT: Read directions for proper use.

18 FL OZ (532 mL)



Drug Facts	
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L0010706BC	

ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-213
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
MENTHOL (UNII: L7T10EIP3A)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM45K49P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLOXAMER 407 (UNII: TUF21VW3M2)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
EDETATE CALCIUM DISODIUM MONOHYDRATE (UNII: PKV6BFV915)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-213-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	05/24/2010	

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(72476-213)