# ANTICAVITY RINSE- 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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# Anticavity Fluoride Rinse, Bubble Gum 004.002/004AE

#### **Active ingredient**

Sodium Fluoride 0.05% (0.2% w/v fluoride ion)

#### **Purpose**

**Anticavity Rinse** 

#### Use

aids in the prevention of dental cavities

### Warnings

## 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 year of age and older: use once a day after brushing your teeth with a toothpaste
- remove cap
- pour 10 milliliters (10 mL mark on inside of cap), do not fill above 10 mL mark
- vigorously swish 10 milliliters 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 year of age: consult a dentist or doctor

#### Other information

store at room temperature

## **Inactive ingredients**

benzyl alcohol, calcium disodium EDTA, cetylpyridinium chloride, disodium EDTA, disodium phosphate, flavor, poloxomer 407, polysorbate 80, propylene glycol, red 33, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water

\*This product is not manufactured or distributed by Chattem, Inc., distributor of Act Kids Anticavity Fluoride Rinse Bubblegum Blowout

Distributed by Foodhold, U.S.A, LLC

4201 Walden Avenue

Landover, MD 20785 1-877-846-9949

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Quality Guaaranteed or your money back

## principal display panel

CAREONE

Compare to Act Kids Anticavity Fluride Rinse\*

CHILDREN'S

**ANTICAVITY** 

**FLUORIDE RINSE** 

Stong Cavity

Protection

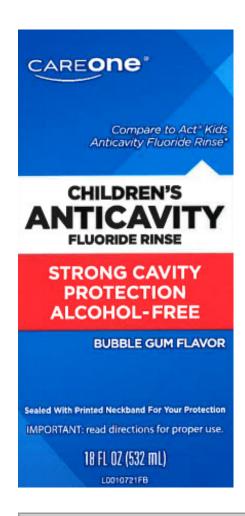
Alcohol Free

**BUBBLE GUM FLAVOR** 

Sealed with printed neckband for your protection

IMPORTANT: Read directions for proper use.

18 FL OZ (532 mL)



## **ANTICAVITY RINSE**

sodium fluoride mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-204
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.5 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
BENZYL ALCOHOL (UNII: LKG8494WBH)		
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)		
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)		
POLOXAMER 407 (UNII: TUF2IVW3M2)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		

D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:72476- 204-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/10/2010	
l		NDC:72476- 204-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/10/2010	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	03/10/2010	

## **Labeler -** Retail Business Services, LLC (967989935)

## Registrant - Vi Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Vi Jon, LLC		790752542	manufacture(72476-204)	

Revised: 1/2023 Retail Business Services, LLC