

ANTICAVITY RINSE- sodium fluoride mouthwash
Rite Aid

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.

Anticavity Fluoride Rinse, Bubble Gum
004.002/004AE

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 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 years 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, poloxamer 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 Bubblegum Blowout Anticavity Kids Fluoride Rinse.

Distributed by:

Rite Aid 30 Hunter Lane,

Camp Hill, PA 170111

www.riteaid.com

SATISFACTION GUARANTEE

If you're not satisfied, we'll happily refund your money.

Principal Panel Display

Sealed with printed neckband for your protection

Compare to Act Bubblegum Blowout Anticavity Kids Fluoride Rinse*

Free From

Alcohol Free

Kids Anticavity

Fluoride Rinse

Bubble Gum Flavor

strong cavity protection

helps strengthen teeth & prevent cavities

fresh & clean

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:11822-4004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium fluoride (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
benzyl alcohol (UNII: LKG8494WBH)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM45K49P)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
poloxamer 407 (UNII: TUF2IVW3M2)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
propylene glycol (UNII: 6DC9Q167V3)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
sodium benzoate (UNII: OJ245FE5EU)	
sodium phosphate (UNII: SE337SVY37)	
saccharin (UNII: FST467XS7D)	
sorbitol (UNII: 506T60A25R)	
water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-4004-4	532 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/05/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	12/05/2022	

Labeler - Rite Aid (014578892)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(11822-4004)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(11822-4004)

Revised: 12/2022

Rite Aid