

ANTICAVITY- sodium fluoride rinse
Wal-Mart

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 Mouthrinse
201.000/201AA

Active ingredient

Sodium fluoride 0.05% (0.02% 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 years and older:

- use once a day after brushing your teeth with toothpaste
- 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, green 3, poloxamer 407, polysorbate 80, propylene glycol, sodium benzoate, sodium phosphate, sorbitol, sucralose, water, yellow 5

Sealed with printed neckband for your protection

Satisfaction guaranteed - Or we'll replace it or give you your money back. For questions or comments or to report an undesired reaction or side effect, please call 1-888-287-1915

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

Distributed by: Wal-Mart Stores, Inc.,

Bentonville, AR 72716 Wal-Mart Stores, Inc.

201.000/201AA

principal display panel

NDC 79903-033-44

Equate

Compare to Act Kids Anticavity Fluoride Rinse Wild Watermelon*

Kids Anticavity Fluoride Rinse

- Alcohol-free
- Paraben-free
- Sugar-free

Watermelon Flavor

IMPORTANT: Read directions for proper use

18 FL OZ (1 PT 2 FL OZ) 532 mL

NDC 79903-033-44

equate™

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to Act Kids
Anticavity Fluoride
Rinse Wild
Watermelon*

Kids

Anticavity

**Fluoride
Rinse**

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**Watermelon
Flavor**

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18 FL OZ (1 PT 2 FL OZ) 532mL

L0019396FA

ANTICAVITY

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79903-033
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	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 ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79903-033-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/19/2020	

Labeler - Wal-Mart (051957769)

Registrant - Vi Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture(79903-033)

