# 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.

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# 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 accidentall 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 unitl 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\*

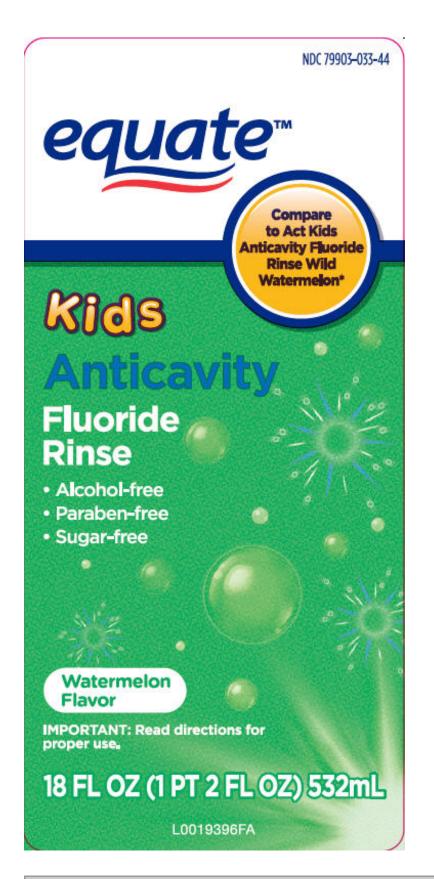
Kids Anticavity Fluoride Rinse

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

Watermelon Flavor

IMPORTANT: Read directions for proper use

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



# 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**

**SODIUM PHOSPHATE** (UNII: SE337SVY37)

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

SORBITOL (UNII: 506T60A25R) **SUCRALOSE** (UNII: 96K6UQ3ZD4) WATER (UNII: 059QF0KO0R)

**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)				
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: 60ZP39ZG8H)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				

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)			

Revised: 12/2022 Wal-Mart