

ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash
Topco Associates, 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.

Anticavity Fluoride Rinse, Mint
213.002/213AE rev 2

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

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

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

Questions?

Call 1-888-423-0139

Adverse reactions

*This product is not manufactured or distributed by Chattem, Inc., distributor of Act Anticavity Fluoride Mouthwash

DISTRIBUTED BY: TOCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

(C) TOPCO VIJ717 QUESTIONS? 1-888-423-0139

topcare@topcare.com www.topcarebrand.com

QUALITY GUARANTEED

This Top Care product is laboratory tested to guarantee its highest quality.

Your total satisfaction is guaranteed.

Principal display panel

COMPARE TO ACT*

TopCare

everyday

ALCOHOL FREE

Anticavity

Fluoride Mouth Rinse

MINT

- Helps prevent cavities
- Helps strengthen teeth
- Freshens breath

IMPORTANT: Read direction for proper use.

ADA Accepted

American Dental Association

- Helps prevent cavities

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

COMPARE TO ACT®*

 **TopCare**®
everyday™

ALCOHOL FREE

Anticavity Fluoride Mouth Rinse

MINT

- **Helps prevent cavities**
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- **Freshens breath**

IMPORTANT:
Read directions for proper use.

L0010708FB
18 FL OZ
(1 PT 2 FL OZ) 532 mL



ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-213	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	0.2 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
water (UNII: 059QF0KO0R)				
sorbitol (UNII: 506T60A25R)				
MENTHOL (UNII: L7T10EIP3A)				
METHYL SALICYLATE (UNII: LAV5U5022Y)				
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
poloxamer 407 (UNII: TUF2IVW3M2)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM PHOSPHATE (UNII: SE337SVY37)				
SODIUM PHOSPHATE, DIBASIC, MONOHYDRATE (UNII: BWZ7K44R51)				
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)				
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:36800-213-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2003	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	10/20/2003		

Labeler - Topco Associates, LLC (006935977)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(36800-213)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(36800-213)

Revised: 5/2023

Topco Associates, LLC