

ANTICAVITY FLUORIDE RINSE- sodium fluoride rinse
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 Top Care_004 004.002/004AE

Active ingredient

Sodium fluoride 0.05% (0.02% w/v fluoride ion)

Purpose

Anticavity rinse

Use

aids in the prevention of dental cavities

Warnings

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 the 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)
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
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- 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 Anticavity Fluoride rinse.

Distributed by: TOPCO ASSOCIATES LLC

7711 GROSS POINT ROAD, SKOKIE, IL 60077

QUESTIONS? 1-888-423-0139

004.002/004AE

principal display panel

TOP CARE

Children's

Alcohol Free

Anticavity

Fluoride

Rinse

- Strong cavity protection
- Helps strengthen teeth
- Helps prevent cavities
- Freshens breath

Bubble Gum Flavor

COMPARE TO ACT

active ingredient

IMPORTANT: READ DIRECTIONS FOR PROPER USE

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

18 FL OZ (532 mL)

TopCare®

Children's

Alcohol Free Anticavity Fluoride Rinse

- Strong cavity protection
- Helps strengthen teeth
- Helps prevent cavities
- Freshens breath

Bubble Gum Flavor

COMPARE TO ACT® active ingredient*

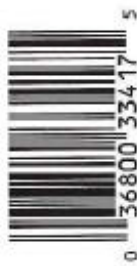
IMPORTANT: READ DIRECTIONS FOR PROPER USE SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

18 FL OZ (532 mL)

L0010697FA

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This TOPCARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

DISTRIBUTED BY: TOPCO ASSOCIATES LLC
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 topcare@topco.com

L0010697BA

ANTICAVITY FLUORIDE RINSE

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-004
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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

SODIUM ACID PYROPHOSPHATE (UNII: H5WVD9LZUD)	
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 SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM (Bubble Gum Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-004-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/08/2004	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	04/08/2004	

Labeler - Topco Associates LLC (006935977)

Registrant - Vi Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture(36800-004)