

ANTICAVITY FLUORIDE RINSE- sodium fluoride rinse
Wakefern Food Corp

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

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)
- supervise children as necessary until capable of using without supervision
- children under 6 years of age: consult a dentist or doctor

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

Other information

- store at room temperature

TEP

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

ADA Statement

"The ADA Council on Scientific Affairs' Acceptance of ShopRite Anticavity Fluoride Rinse is based on the finding that the product is effective in helping to prevent and reduce tooth decay, when used as directed"

Questions or Comments

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

Qw welcome your questions and comments.

Call: 1-800-ShopRite

E-mail: www.shoprite.com

Write:: Wakefern Food Corp.

600 York St.

Elizabeth, NJ 07027

Please provide product UPC and codes stamped on product

Adverse Reactions Section

DISTRIBUTED BY

WAKEFERN FOOD CORPORATION

5000 RIVERSIDE DRIVE

KEASBEY, NJ 08832

004.002/024AE

Principal Display Panel

Compare to the active ingredient in ACT

Shop Rite

Anticavity

FLUORIDE

RINSE

FOR KIDS

Strong Cavity

Protection

Alcohol Free

BUBBLE GUM BLAST

ADA

ACCEPTED

American

Dental

Association

IMPORTANT: Read directions for proper use

18 FL OZ (532 mL)



ANTICAVITY FLUORIDE RINSE

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-104
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)	
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
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: 059QF0K00R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41190-104-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/19/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/19/2007	

Labeler - Wakefern Food Corp (069722418)

Registrant - Vi Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture(41190-104)