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

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

ADA Statement

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

Questions or Comments

This product is not manufactured or distributed by Chattem, Inc., dostributor 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

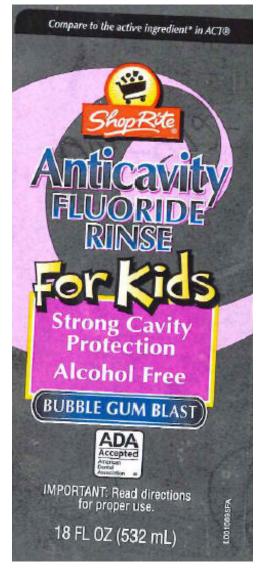
Compare to the active ingredient in ACT Shop Rite Anticavity FLUORIDE RINSE FOR KIDS Strong Cavity Protection Alcohol Free BUBBLE GUM BLAST ADA ACCEPTED American

Dental

Association

IMPORTANT: Read directions for proper use

18 FL OZ (532 mL)



ANTICAVITY FLUORIDE RINSE								
sodium fluoride rinse								
Product Information								
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:41190-104				
Route of Administration	ORAL							
Active Ingredient/Active Moiety								
In	Basis of Strength		Strength					
SODIUM FLUORIDE (UNII: 8ZYQ147	FLUORIDE ION		0.2 mg in 1 mL					

Inactive Ingree	Ingredient Name			Strength
BENZYL ALCOHO	L (UNII: LKG8494WBH)			
EDETATE CALCIU	M DISO DIUM (UNII: 25IH6 R4SGF)			
CETYLPYRIDINIU	M CHLORIDE (UNII: D9OM4SK49P)			
EDETATE DISODI	U M (UNII: 7FLD91C86K)			
POLOXAMER 407	(UNII: TUF2IVW3M2)			
POLYSORBATE 8	0 (UNII: 6OZP39ZG8H)			
PROPYLENE GLY	COL (UNII: 6DC9Q167V3)			
D&C RED NO.33 (UNII: 9DBA0SBB0L)			
SODIUM BENZOA	TE (UNII: OJ245FE5EU)			
SO DIUM PHO SPH	ATE (UNII: SE337SVY37)			
SACCHARIN SODI	UM (UNII: SB8ZUX40TY)			
SORBITOL (UNII: S	506T60A25R)			
Product Chara Color Shape			Score Size	
Flavor Contains	BUBBLE GUM (Bubble Gum Blast)		Imprint Code	
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	tio n	10/19/2007	
	nformation			
Marketing I				
Marketing I Marketing Categ		n Ma	arketing Start Date	Marketing End Date

Labeler - Wakefern Food Corp (069722418)

Registrant - Vi Jon (790752542)

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