ANTICAVITY RINSE- sodium fluoride mouthwash Walgreen Co

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 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 10mL 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

Adverse reaction

Sealed with printed neckband for your protection

*This product is not manufactured or distributed by Chattem, Inc., distributor of Act Anticavity Fluoride Rinse. Questions or comments? 1-800-925-4733

Distributed by: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015

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Patent D604,628

004.002/004AE

principal display panel

Well at Walgreens

children's

ANTICAVITY - FLUORIDE

Mouth Rinse

Anticavity Fluoride Rinse

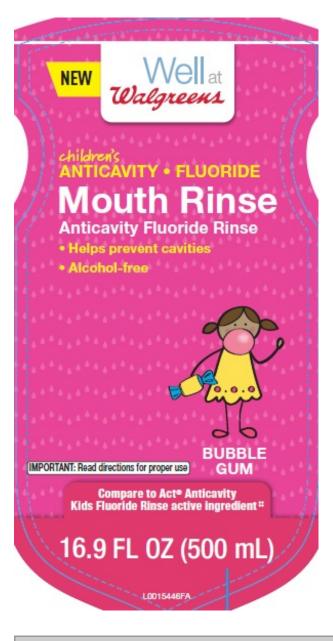
Helps prevent cavities

- Alcohol-free
- BUBBLE GUM

IMPORTANT: Read drections for proper use

Compae to Act Anticavity Kids Fluoride Rinse active ingredient

16.9 FL OZ (500 mL)



ANTICAVITY RINSE

sodium fluoride mouthwash

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:0363-0014		0363-0014	
Route of Administration	ORAL				
Active Ingredient/Active Meiety					
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Stre	ngth	Strength
SODIUM FLUORIDE (UNII: 8ZYQ14	74W7) (FLUORIDE ION - UNI	I:Q80VPU408O)	FLUORIDE ION		.05 kg in 100 L
Inactive Ingredients					
	Ingredient Name				Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)					

CETYLPYRIDINIU	M CHLORIDE (UNII: D9OM4SK49P)			
EDETATE DISOD	IUM (UNII: 7FLD91C86K)			
SODIUM PYROPI	IOSPHATE (UNII: O352864B8Z)			
POLOXAMER 40	(UNII: TUF2IVW3M2)			
POLYSORBATE 8	0 (UNII: 60ZP39ZG8H)			
PROPYLENE GLY	COL (UNII: 6DC9Q167V3)			
D&C RED NO. 33	(UNII: 9DBA0SBB0L)			
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM PHOSPI	HATE (UNII: SE337SVY37)			
SACCHARIN SOD	IUM (UNII: SB8ZUX40TY)			
SORBITOL (UNII:	506T60A25R)			
WATER (UNII: 059	QF0KO0R)			
Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:0363-	.5 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/27/2002		

Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph finalpart35506/27/2002

Labeler - Walgreen Co (008965063)

Registrant - Vi Jon, LLC (790752542)

Establishment					
Name	Address	ID/FEI	Business Operations		
Vi Jon, LLC		790752542	manufacture(0363-0014)		
Establishme	nt				
Name	Address	ID/FEI	Business Operations		

Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		088520668	manufacture(0363-0014)

Revised: 12/2022

Walgreen Co