ORAL ANTIVAVITY- sodium fluoride mouthwash Wal-Mart Stores, Inc

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.

Mint MW 576.001/576AC

Claims

Alcohol Free

Anticavity

Oral Rinse

Safety Seal

Sealed with printed neckband for your protection

Active ingredient

Sodium fluoride 0.0219% (0.01% w/v fluoride ion)

Purpose

Anticavity

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, get medical help or contact a Poison Control Center Right Away

Directions

Adults and children 6 years of age and older:

• use twice daily after brushing your teeth with a toothpaste

- vigorously swish 10 mL (2 teaspoonfuls) of rinse bwtween your teeth for 1 minute 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 witout supervision
- children under 6 years of age: consult a dentist or doctor

Inactive ingredients

water, glycerin, flavor, cetylpyridinium chloride, sodium saccharin, phosphoric acid, sodium benzoate, sucralose, poloxamer 407, benzoic acid, disodium phosphate, propylene glycol, blue 1

Questions?

Call 1-888-287-1915

Claims

This rinse may cause temporary staining to the surface of teeth. This is not harmful, add adequate brushing may prevent its occurrence.

Satisfaction

Satisfaction guaranteed-Or wel'll replace it or give you your money back. For questions or comments or to report an undesired reaction or side effect, pleace call 1-888-287-1915

Adverse Reactions

Distributed by: Wal-Mart Stores, Inc., Bentonville, Ar 72716

576.000/576AB

Disclaimer

This product is not manufactured or distributed by Procter & Gamble, distributor of Crest Pro-Health Complete Anticavity Fluoride rinse.

principal display panel

equate

Compare to Crest Pro Health Anticavity Fluoride Rinse

IMPORTANT: READ DIRECTINS FOR PROPER USE

Alcohol Free

Anticavity

Oral Rinse

Multi-Action with Fluoride

- Cleans teeth
- Helps prevent cavities
- Helps strengthen enamel
- Kills bad breath germs
- Helps keep mouth feeling clean
- Freshens breath
- No burn of alcohol

Refreshing Mint

1 L (33.8 FL OZ)





ORAL ANTIVAVITY

sodium fluoride mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-576
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII: Q80VPU408O)	FLUORIDE ION	10.41 mg in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
PHOSPHORIC ACID (UNII: E4GA8884NN)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
BENZOIC ACID (UNII: 85KN0B0MIM)				
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:49035- 576-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/08/2015	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	01/08/2015		

Labeler - Wal-Mart Stores, Inc (051957769)

Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(49035-576)	

Revised: 12/2022 Wal-Mart Stores, Inc