

ORAL ANTICAVITY- sodium fluoride mouthwash

Topco

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.

Whitening Anticavity Rinse

576.001/576AC

claims

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECION

TopCare

everyday

- Helps strengthen enamel
- Helps prevent cavities
- Kills bad breath germs
- Freshen Breath

active ingredient

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

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warnings

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 without 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 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

©TOPCO VIJA0122 QUESTIONS? 1-888-423-0139

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

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

This product is not intended to replace brushing or flossing

Principal display panel

COMPARE TO CREST PRO-HEALTH ADVANCED ANTICAVITY FLUORIDE MOUTHWASH

TopCare

everyday

ALCOHOL FREE

Fluoride

Anticavity Mouthwash

REFRESHING MINT

- Helps strengthen enamel
- Helps prevent cavities
- Cleans teeth**
- Kills bad breath germs
- Freshens breath
- Helps keep mouth feeling clean

IMPORTANT: Read directions for proper use.

33.8 FL OZ (1 QT 1.8 FL OZ) 1 L



ORAL ANTIVAVITY

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-576
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)			FLUORIDE ION	10.41 mg in 1 mL
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
CETYLPIRIDINIUM 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: 8SKN0B0MIM)				
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
1	NDC:76162-576-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/04/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	04/04/2022		

Labeler - Topco (006935977)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(76162-576)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(76162-576)

