

ORAL ANTICAVITY- sodium fluoride mouthwash
HARRIS TEETER, LLC

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.

Alcohol Free Fluoride Refreshing Mint Mouthwash
576.001/576AC-AD

Active ingredient

Sodium fluoride 0.02% (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 between 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 1-888-593-0593

Claims

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 Proctor and Gamble, distributor of Crest Pro-Health Advanced Anticavity Fluoride Mouthwash.

Adverse Reactions

PROUDLY DISTRIBUTED BY:

HARRIS TEETER, LLC, MATTHEWS, NC 28105

1-800-432-6111 or harristeeter.com

Principal display panel

Harris Teeter

Sealed with printed neckband for your protection

Compare to Crest Pro-Health Advanced*

Refreshing Mint

Fluoride

Alcohol Free

Mouth Rinse

Anticavity Mouthwash

- KILLS GERMS THAT CAUSE BAD BREATH
- HELPS PREVENT CAVITIES

IMPORTANT: READ DIRECTIONS FOR PROPER USE

1 L (1.05 qt) 33.8 FL OZ



ORAL ANTIVAVITY

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72036-576
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETILPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

PHOSPHORIC ACID (UNII: E4GA8884NN)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POLOXAMER 407 (UNII: TUF21VW3M2)	
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:72036-576-86	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 - HARRIS TEETER, LLC (047279351)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72036-576)

Revised: 5/2023

HARRIS TEETER, LLC