

ANTICAVITY RINSE- sodium fluoride mouthwash H-E-B

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, Bubble Gum 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 year 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 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 year of age: consult a dentist or doctor

Other information

- store at room temperature

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

MADE WITH PRIDE AND CARE FOR H-E-B,

San Antonio, TX 78204

100% GUARANTEE promise

If you aren't completely

pleased with this product, we'll be happy to replace it or refund your money.

You have our word on it.

how2recycle.com

US ONLY

Discard Seal, Empty & Replace Cap

Principal display panel

ADA

Accepted

American

Dental

Association

Helps prevent cavities

Sealed with printed neckband for your protection

H-E-B

BUBBLEGUM

Anticavity

Fluoride Mouthwash

Helps prevent cavities

IMPORTANT: read directions for proper use

18 FL OZ (1.13 PT) 532 mL



ANTICAVITY RINSE

sodium fluoride mouthwash

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:37808-808

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
POLOXAMER 407 (UNII: TUF21VW3M2)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-808-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/25/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/25/2010	

Labeler - H-E-B (007924756)

Registrant - Vi Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		790752542	manufacture(37808-808)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		088520668	manufacture(37808-808)

Revised: 4/2023

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