

ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash HEB

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

Active ingredient

Sodium Fluoride 0.05% (0.02% w/v fluoride ion)

Purpose

Anticavity Rinse

Use

aids in the prevention of dental cavities

Warning

for this product only

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 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 years 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, green 3, menthol, methyl salicylate, poloxamer 407, polysorbate 20, potassium sorbate, propylene glycol, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water, yellow 5.

Questions?

Call 1-888-593-0593

ADA Council Statement

"The ADA Council on Scientific Affairs Acceptance of HEB Anticavity Fluoride Rinse is based on its finding that the product is effective in helping to prevent and reduce tooth decay, when used as directed."

Disclaimer

This product is not manufactured or distributed by Chattem, Inc., distributor of Act Anticavity Fluoride Mouthwash

TEP

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Adverse reactions

MADE WITH PRIDE AND CARE FOR H-E-B SAN ANTONIO, TX 78204

Principal Display Panel

Compare to ACT Anticavity

Fluoride Mouthwash

H-E-B

Mint

ANTICAVITY

FLUORIDE

MOUTH RINSE

ADA

Accepted

American

Dental

Association

- Helps Prevent Cavities
- Alcohol Free
- Freshens Breath

IMPORTANT: read directions for proper use.

18 FL OZ (1.1 PT) 532 mL



ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-213
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)	
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
menthol (UNII: L7T10EIP3A)	

methyl salicylate (UNII: LAV5U5022Y)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-213-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/21/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/21/2016	

Labeler - HEB (007924756)

Registrant - Vi-Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(37808-213)