

ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash

HEB

HEB 213.002/213AE Rev 2
Anticavity Fluoride Rinse, Mint

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

water, sorbitol, menthol, methyl salicylate, flavor, cetylpyridinium chloride, sodium saccharin, poloxamer 407, polysorbate 20, propylene glycol, sodium phosphate, disodium phosphate, calcium disodium EDTA, disodium EDTA, sodium benzoate, potassium sorbate, benzyl alcohol, green 3, yellow 5

Questions?

Call 1-888-593-0593

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

100% Guarantee promise

Principal Display Panel

Compare to ACT Anticavity

Fluoride Mouthwash

H-E-B

Mint

ANTICAVITY

FLUORIDE

MOUTH RINSE

- Helps Prevent Cavities
- Alcohol Free
- Freshens Breath

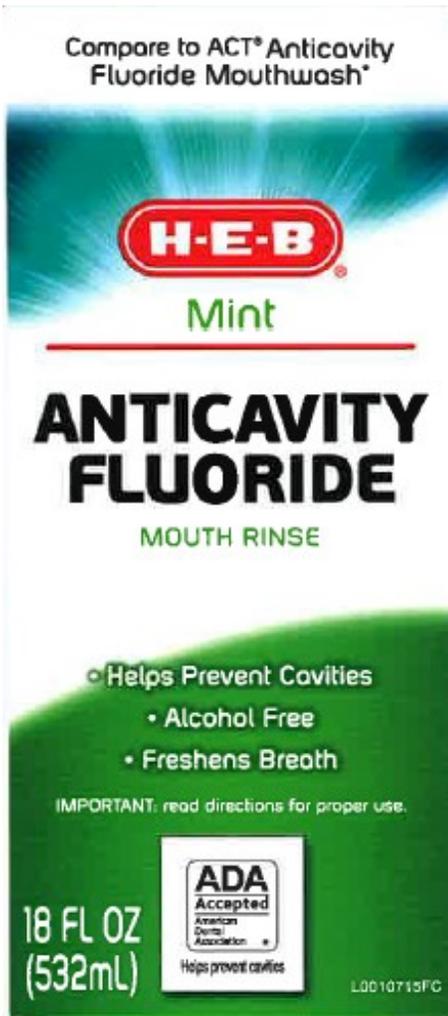
IMPORTANT: read directions for proper use.

ADA Accepted

American Dental Association

Helps prevent cavities

18 FL OZ (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
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	

CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)
SACCHARIN SODIUM (UNII: SB8ZUX40TY)
POLOXAMER 407 (UNII: TUF2IVW3M2)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SODIUM PHOSPHATE (UNII: SE337SVY37)
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)
EDETATE DISODIUM (UNII: 7FLD91C86K)
SODIUM BENZOATE (UNII: OJ245FE5EU)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
BENZYL ALCOHOL (UNII: LKG8494WBH)
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)
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 Drug	M021	06/21/2016	

Labeler - H E B (007924756)

Registrant - Nice-Pak Products, LLC (119091520)

Establishment

Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(37808-213)