

ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash
United Natural Foods, Inc. dba UNFI

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, Mint
213.001/213AE rev 2

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

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

Sealed with printed Neckband for your protection

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

Like it or Let us make it right.

That's our quality promise.

855-423-2630

DISTRIBUTED BY UNFI

PROVIDENCE, RI 02908 USA

Principal Panel Display

NDC 41163-213-44

comapre to Act Anticavity Fluoride Rinse active ingredient*

EQUALINE

anticavity

fluoride

rinse

- does not contain ethyl alcohol
- helps prevent cavities
- helps strengthen tetth
- freshens breath

mint

INPORTANT: READ DIRECTIONS FOR PROPER USE.

18FL OZ (532mL)

NDC 41163-213-44

compare to
Act® Anticavity
Fluoride Rinse
active ingredient*

EQUALINE®

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- does not contain ethyl alcohol
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mint

IMPORTANT: READ DIRECTIONS FOR PROPER USE,

L0021031FA

18 FL OZ (532 mL)

ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-213
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
MENTHOL (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 ANHYDROUS (UNII: 8NLQ36F6MM)	
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:41163-213-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/14/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/14/2009	

Labeler - United Natural Foods, Inc. dba UNFI (943556183)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(41163-213)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		088520668	manufacture(41163-213)