

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

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**Equaline 213.001/213AE 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

**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

## **ADVERSE REACTION**

Sealed with printed neckband for your protection

\*This product is not manufactured or distributed by Chattem, Inc., distributor of Act<sup>®</sup> 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<sup>®</sup> Anticavity Fluoride Rinse active ingredient\*

EQUALINE<sup>®</sup>

anticavity

fluoride

rinse

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

mint

INPORTANT: READ DIRECTIONS FOR PROPER USE.

18 FL OZ (532 mL)

NDC 41163-213-44

compare to  
**Act® Anticavity  
Fluoride Rinse**  
active ingredient\***EQUALINE®****anticavity  
fluoride  
rinse**

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

**mint**

IMPORTANT: READ DIRECTIONS FOR PROPER USE.

L0021031FA

**18 FL OZ (532 mL)****Drug Facts**

Active ingredient	Purpose
Sodium fluoride 0.05% (0.02% w/v fluoride ion)	Anticavity rinse

**Use** aids in the prevention of dental cavities**Warning****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
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- 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, polyacrylate 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**

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PROVIDENCE, RI 02908 USA**

L0021031BA

**ANTICAVITY FLUORIDE RINSE**

sodium fluoride mouthwash

**Product Information**

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

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.2 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)	

<b>CETYLPYRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P)
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)
<b>POLOXAMER 407</b> (UNII: TUF2IWW3M2)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)
<b>EDETATE CALCIUM DISODIUM ANHYDROUS</b> (UNII: 8U5D034955)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)
<b>FD&amp;C YELLOW NO. 5</b> (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 Drug	M021	05/14/2009	

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

**Registrant** - Nice-Pak Products, LLC (119091520)

### Establishment

Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(41163-213)

Revised: 2/2026

United Natural Foods, Inc. dba UNFI