

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

Equaline 581.000/581AC
Restoring Anticavity Fluoride Mouthwash

Active ingredient

Sodium fluoride 0.02% (0.009% w/v fluoride ion)

Purpose

Anticavity

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, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 6 years of age and older:

- use twice a day after brushing your teeth with a toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) 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

Inactive ingredients

water, alcohol (11%), sorbitol, poloxamer 407, propylene glycol, sodium benzoate, flavor, sodium phosphate, polysorbate 20, sodium saccharin, cetylpyridinium chloride, disodium phosphate, calcium disodium EDTA, blue 1

Tamper Evident Statement

Sealed With Printed Neckband For Your Protection

Disclaimer

*This product is not manufactured or distributed by Chattem Inc., distributor of Act Restoring Anticavity Mouthwash Cool Mint

Adverse reaction

Like it or let us make it right.

That is our quality promise.

855-423-2630

DISTRIBUTED BY UNFI

PROVIDENCE, RI 02908 USA

DSP-TN-21091

DSP-MO-20087

Principal panel display

compare to Act [®]Restoring Anticavity Fluoride Mouthwash*

EQUALINE [®]

restoring

anticavity

fluoride

mouthwash

- restores enamel
- helps avoid tooth decay

refreshing mint

IMPORTANT: READ DIRECTIONS FOR PROPER USE

33.8 FL OZ (1.05 QT) 1 L

compare to
Act® Restoring
Anticavity Fluoride
Mouthwash*

EQUALINE®

restoring
**anticavity
fluoride
mouthwash**

- restores enamel
- helps avoid tooth decay



refreshing mint

IMPORTANT: READ DIRECTIONS FOR PROPER USE.

L0019562FA

33.8 FL OZ (1L)

Drug Facts

| Active ingredient | Purpose |
|---|------------|
| Sodium fluoride 0.02% (0.008% w/v fluoride ion) | Anticavity |

Use aids in the prevention of dental cavities

Warning

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Directions

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DSP-TN-21091
DSP-MO-20087



0 41163 50310 6

L0019562BA

ANTICAVITY

sodium fluoride mouthwash

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41163-581 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| SORBITOL (UNII: 506T60A25R) | |
| POLOXAMER 407 (UNII: TUF21VW3M2) | |

| | |
|--|--|
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SODIUM PHOSPHATE (UNII: SE337SVY37) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) | |
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) | |
| EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:41163-581-86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/26/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M021 | 10/26/2020 | |

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(41163-581) |

Revised: 2/2026

United Natural Foods, Inc. dba UNFI