

ALCOHOL-FREE ANTICAVITY- sodium fluoride liquid
Retail Business Services, LLC

Care One 482.002/482AC
Alcohol Free Fluoride Violet Mint Mouthwash

TEP

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Active ingredient

Sodium fluoride 0.02% (0.01% 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 daily 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, glycerin, cetylpyridinium chloride, flavor, cinnamal, sodium saccharin, phosphoric acid, sodium benzoate, sucralose, poloxamer 407, benzoic acid, disodium phosphate, propylene glycol, red 33, green 3

Disclaimer

This rinse may cause temporary staining to the surface of teeth.

This is not harmful, and adequate brushing may prevent its occurrence.

*This product is not manufactured or distributed by Procter & Gamble, distributor of Crest[®] Pro-Health[®] Advanced Anticavity Fluoride Mouthwash Enamel Care Alcohol Free.

**This product is not intended to replace brushing or flossing.

Adverse reaction

DISTRIBUTED BY: ADUSA DISTRIBUTION, LLC

SALISBURY, NC 28147

For product questions or concerns, contact us at 1-833-992-3872

Quality guaranteed or your money back.

Principal display panel

CAREONE[®]

Compare to the Active Ingredient in Crest[®] Pro-Health[®] Advanced Anticavity Fluoride Mouthwash*

ALCOHOL FREE

FLUORIDE MOUTHWASH

ANTICAVITY

FLUORIDE RINSE

VIOLET MINT FLAVOR

KILLS BAD BREATH GERMS

HELPS PREVENT CAVITIES

HELPS STRENGTHEN ENAMEL

CLEANS TEETH**

FRESHENS BREATH

IMPORTANT: Read directions for proper use

33.8 FL OZ (1.05 QT) 1L

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in Crest[®] Pro-Health[®] Advanced
Anticavity Fluoride Mouthwash**

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L0012634FD

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Drug Facts

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|--|------------|
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ALCOHOL-FREE ANTICAVITY

sodium fluoride liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72476-482 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 0.1 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CETYLPYRIDINIUM CHLORIDE (UNII: D9OM45K49P) | |
| CINNAMALDEHYDE (UNII: SR60A3XG0F) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| PHOSPHORIC ACID (UNII: E4GA8884NN) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| POLOXAMER 407 (UNII: TUF2IVW3M2) | |
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| D&C RED NO. 33 (UNII: 9DBA05BB0L) | |
| WATER (UNII: 059QF0KO0R) | |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72476-482-86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/03/2013 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M021 | 02/01/2013 | |

Labeler - Retail Business Services, LLC (967989935)

Registrant - Nice-Pak Products, LLC (119091520)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|------------------------|
| Nice-Pak Products, LLC | | 119091514 | manufacture(72476-482) |

