**ANTISEPTIC- cetylpyridinium chloride rinse**
**Topco Associates LLC**

*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.*

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**Antiseptic mouthrinse**
**299**

**Active ingredient**

Cetylpyridinium chloride 0.07%

**Purpose**

Antigingivitis, Antiplaque

**USE**

helps control plaque that leads to gingivitis

**Warnings**

for this product only

**Stop use and ask a dentist if**

- gingivitis, bleeding or redness persists for more than 2 weeks
- you have painful or swollen gums, pus from the gun line, loose teeth or increased spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

**Keep out of reach of children under 6 years of age.**

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 & older: rinse for 30 seconds with 20 mL (4 teaspoonfuls) twice a day
- do not swallow
- children 6 years to under 12 years of age: supervise use
- children under 6 years of age: do not use

**other information**

- this rinse is not intended to replace brushing or flossing

**Inactive ingredients**

water, glycerin, flavor, poloxamer 188, sodium saccharin, propylene glycol, sodium benzoate, sucralose, benzoic acid, blue 1

*This product is not manufactured or distributed by Procter & Gamble distributor of Crest Pro-Health Rinse

DISTRIBUTED BY TOPCO ASSOCIATES, LLC

ELK GROOVE VILLAGE, IL 60077

QUESTIONS? 1-888-423-0139

topcare@topcare.com

299.005/299AK

**principal display panel**

Sealed With Printed Neckband For Your Protection

TopCare

ALCOHOL FREE

Oral Health Rinse

ANTISEPTIC

Antigingivitis/Antiplaque

Kills germs
Helps prevent plaque
Helps prevent gingivitis
Helps keep teeth feeling clean
No burn of alcohol
Freshens breath
Mint Flavor

QUALITY GUARANTED

COMPARE TO ACTIVE INGREDIENT OF CREST PRO-HEALTH RINSE*

33.8 FL OZ (1 QT 1.8 FL OZ) 1 L


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Neckband For Your Protection
ALCOHOL
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33.8 FL OZ
(1 QT 1.8 FL OZ) 1L

**ANTISEPTIC**

cetylpyridinium chloride rinse

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:36800-299 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **CETYLPYRIDINIUM CHLORIDE** (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7JI0JV3) | CETYLPYRIDINIUM CHLORIDE | 0.7 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **POLOXAMER 188** (UNII: LQA7B6G8JG) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |
| **BENZOIC ACID** (UNII: 8SKN0B0MIM) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:36800-299-86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/03/1993 | |
| **2** | NDC:36800-299-21 | 89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/03/1993 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part356 | 08/03/1993 | |

## Labeler - Topco Associates LLC (006935977)

## Registrant - Vi-Jon (790752542)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Vi-Jon | | 790752542 | manufacture(36800-299) |