

**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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**TopCare Antiseptic mouthrinse**  
**299.005/295AK/AL**

**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 gum 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

## **Questions?**

Call 1-888-423-0139

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

TopCare everyday

- Kills germs for better oral hygiene
- Helps reduce plaque bacteria
- Helps prevent gingivitis
- Freshens breath

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 Multi-Protection Alcohol Free Rinse-Refreshing Clean Mint

DISTRIBUTED BY TOPCO ASSOCIATES, LLC

ELK GROOVE VILLAGE, IL 60077

QUESTIONS? 1-888-423-0139

topcare@topcare.com www.topcarebrand.com

This Top Care product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

## **principal display panel**

COMPARE TO CREST PRO-HEALTH MOUTH RINSE

TopCare everyday

ALCOHOL FREE ORAL HEALTH Mouthwash

ANTINGIVITIS / ANTIPLAQUE

MINT

- Kills germs for better oral hygiene
- Helps reduce plaque bacteria
- Helps prevent gingivitis
- Freshens breath

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



## ANTISEPTIC

cetylpyridinium chloride rinse

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-299
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7J10JV3)		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	
3	NDC:36800-299-86	1000 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, LLC (790752542)

### Establishment

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

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(36800-299)

