

ALCOHOL FREE ANTISEPTIC ORAL- 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.

Drug Facts
223

Active ingredient

Cetylpyridinium chloride 0.07%

Purpose

Antigingivitis, Antiplaque

Use

helps control plaque that leads to gingivitis

Warnings

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
- when used after brushing, rinse mouth with water first
- 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, propylene glycol, flavor, poloxamer 188, methylparaben, propylparaben, sodium saccharin, citric acid, yellow 6, green3

Sealed with printed neckband for your protection

TOP CARE

This TOP CARE product is laboratory tested to guarantee its highest quality.
Your total satisfaction is guaranteed.

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

DISTRIBUTED BY TOPCO ASSOCIATES LLC
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ALCOHOL FREE

Antiseptic ORAL RINSE

ANTIINGIVITIS/ANTIPLAQUE

•Kills germs that cause bad breath, plaque and the gum disease gingivitis

Mint Flavor

COMPARE TO ACTIVE INGREDIENT OF CREST PRO-HEALTH RINSE*

1 L (33.8 FL OZ)



ALCOHOL FREE ANTISEPTIC ORAL

cetylpyridinium chloride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-223
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7J10JV3)	CETYLPYRIDINIUM CHLORIDE	0.07 mg in 100 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLOXAMER 188 (UNII: LQA7B6G8JG)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C GREEN NO. 3 (UNII: 3P3ONR60IS)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-223-86	1 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/1990	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/15/1990	

Labeler - Topco Associates LLC (006935977)**Registrant** - Vi-Jon (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(36800-223)

