

EMERALD MINT HEALTH- cetylpyridinium chloride mouthwash
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
339

Active ingredient

Cetylpyridinium Chloride 0.07%

Purpose

Antigingivitis/Antiplaque

Use

helps control plaque that leads to gingivitis

Warnings

For this product

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 12 years + older: vigorously swish 20 mL (4 teaspoonfuls) of rinse between your teeth twice a day for 30 seconds and then spit out
- 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, alcohol (10.8wt%), glycerin, propylene glycol, flavor, poloxamer 407, sodium saccharin, yellow 6, green 3

Top Care Oral Health Antiseptic Mouth Rinse

*This product is not manufactured or distributed by Procter + Gamble, distributor of Crest Pro-health Invigorating Clean Multi-Protection Oral Rinse

This rinse may cause temporary staining to the surface of the teeth. This is not harmful, and adequate brushing may prevent its occurrence.

DISTRIBUTED BY TOPCO ASSOCIATES LLC

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DSP-TN-1500 DSP-MO-34 SDS-TN-15012

Principal Display Panel

Sealed With Printed Neckband For Your Protection

EMERALD MINT

Oral Health

Antiseptic Mouth Rinse

Antigingivitis/Antiplaque

- Promotes fresh breath while fighting gingivitis
- Helps keep teeth feeling clean
- Helps keep breath fresh

COMPARE TO CREST Pro-Health Invigorating Clean Multi-Protection Oral Rinse

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



EMERALD MINT HEALTH

cetylpyridinium chloride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-015
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYL PYRIDINIUM - UNII: CUB7J10JV3)	CETYL PYRIDINIUM CHLORIDE	0.07 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-015-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/19/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/19/2013	

Labeler - TopCo Associates LLC (006935977)

Registrant - Vi-Jon (790752549)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(36800-015)