

ANTISPETIC- cetylpyridinium chloride liquid

Demoulas Super Markets

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

claims

For better oral hygiene and fresher breath.

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 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, flavor, poloxamer 188, sodium saccharin, propylene glycol, methylparaben, sucralose, propylparaben, blue1

disclaimer

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

Adverse Reaction

DISTRIBUTED BY

DEMOULAS SUPER MARKETS, INC.

875 EAST STREET

TEWKSBURY, MA 01876

Principal Display Panel

MORE FOR YOUR DOLLAR

MARKET BASKET

Sealed with printed

neckband for your protection

Compare to active ingredient in Crest Pro-Health Rinse

Multit-Action

Alcohol-Free

Antiseptic

Oral Rinse

with CPC

Antigingivitis/Antiplaque

- KILLS GERMS
- HELPS PREVENT PLAQUE
- HELPS PREVENT GINGIVITIS
- HELPS KEEP TEETH FEELING CLEAN
- FRESHENS BREATH
- NO BURN OF ALCOHOL

Zesty Mint

1 L (33.8 FL OZ)

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L0004794FB

ANTISPETIC

cetylpyridinium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53942-299
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	0.7 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLO XAMER 188 (UNII: LQA7B6G8JG)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53942-299-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/21/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/21/2012	

Labeler - Demoulas Super Markets (007869647)**Registrant** - Vi-Jon (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(53942-299)