

**HEALTH- cetylpyridinium chloride mouthwash**  
**DOLGENCORP, 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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**Drug facts**

**Claims**

Sealed With Printed Neckband For Your Protection

MULTI-ACTION

ALCOHOL-FREE

ORAL

RINSE

Antigingivitis/Antiplaque

Use 2X/Day for

better oral hygiene

**Active ingredients**

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 secnds 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, sodium benzoate, sucralose, benzoic acid, blue 1

#### **Disclaimer**

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

#### **Adverse Reactions**

DISTRIBUTED BY

DOLGENCORP, LLC

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

100% Satisfaction Guaranteed (888)309-9030

299.005/299AK

#### **Principal Display Panel**

DG health

Compare to Crest Pro-Health

Multi-Protection Alcohol Free rinse

Use

2X/Day

for better oral hygiene

MULTI-ACTION

ALCOHOL-FREE

ORAL RINSE

Antigingivitis/Antiplaque

FRESH MINTY FLAVOR

MULTIPLE BENEFITS

- Kills Germs

- Freshens Breath
- Helps Prevent Plaque & Gingivitis
- Helps Keep Teeth Feeling Clean

1 L (33.8 FL OZ)

**DG** | health

Compare to Crest® Pro-Health®  
Multi-Protection Alcohol Free Rinse\*

Use  
**2X/Day**  
for better oral hygiene

**MULTI-ACTION  
ALCOHOL-FREE**

# **ORAL RINSE**

Antigingivitis / Antiplaque

**FRESH MINTY FLAVOR**

## **MULTIPLE BENEFITS**

- Kills Germs
- Freshens Breath
- Helps Prevent  
Plaque & Gingivitis
- Helps Keep Teeth  
Feeling Clean

**1 L (33.8 FL OZ)**

## **HEALTH**

cetylpyridinium chloride mouthwash

**Product Information**

|                                |                |                           |                 |
|--------------------------------|----------------|---------------------------|-----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:559 10 -299 |
| <b>Route of Administration</b> | ORAL           |                           |                 |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7J10JV3) | CETYLPYRIDINIUM CHLORIDE | 0.7 mg in 1 mL  |

**Inactive Ingredients**

| <b>Ingredient Name</b>              | <b>Strength</b> |
|-------------------------------------|-----------------|
| 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: 8SKN0B0MM)      |                 |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)  |                 |

**Packaging**

| # | Item Code            | Package Description   | Marketing Start Date | Marketing End Date |
|---|----------------------|---|----------------------|--------------------|
| 1 | NDC:559 10 -299 - 86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/21/2008           |                    |

**Marketing Information**

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part356                                  | 07/21/2008           |                    |

**Labeler** - DOLGENCORP, LLC (068331990)**Registrant** - Vi-Jon (790752542)**Establishment**

| Name   | Address | ID/FEI    | Business Operations      |
|--------|---------|-----------|--------------------------|
| Vi-Jon |         | 790752542 | manufacture(559 10 -299) |