

## **ANTISEPTIC- cetylpyridinium chloride 0.07% mouthwash**

**Hy-Vee, Inc**

*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**

#### **Warning**

**SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION**

#### **Claims**

HyVee

#### **Antiseptic**

#### **Mouth Rinse**

#### **Alcohol-Free**

□For better oral hygiene and fresher breath

#### **Active Ingredients**

##### **Active ingredients**

Cetylpyridinium chloride 0.07%

#### **Purpose**

##### **Purpose**

Antigingivitis, Antiplaque

#### **Use**

Use helps control plaque that leads to gingivitis

#### **Warnings**

##### **Warnings**

#### **Stop use section**

##### **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**

**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**

### **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 informatin**

#### **Other information**

- this rinse is not intended to replace brushing or flossing

### **Inactive ingredients**

**Inactive ingredients** water, glycerin, flavor, poloxamer 188, sodium saccharin, propylene glycol, methylparaben, sucralose, propylparaben, blue 1

### **Disclaimer**

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

### **Adverse reactions**

DISTRIBUTED BY HY-VEE, INC., WEST DES MOINES, IA 50266

SATISFACTION GUARANTEED, CALL 1-800-289-8343

[www.hy-vee.com](http://www.hy-vee.com)

### **Principal Display Panel**

Hy-Vee

Antiseptic

MOUTH RINSE

ALCOHOL-FREE

Zesty Mint

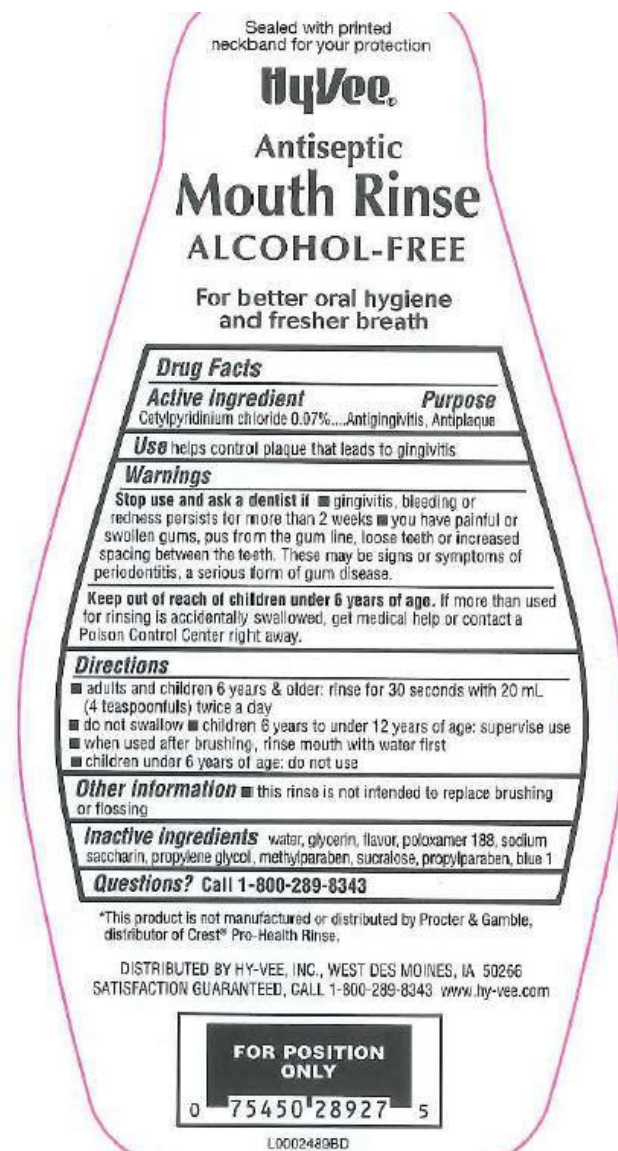
Antigingivitis/Antiplaque

- Kills germs
- Helps prevent
- Helps prevent gingivitis
- Helps keep teeth feeling clean
- Freshen breath
- No burn of alcohol

15.390625px15.390625pxCompare to active ingrediet in Crest Pro-Health rinse

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ANTISEPTIC		
cetylpyridinium chloride 0.07% mouthwash		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)
Route of Administration	ORAL	NDC:42507-299
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7JJ0JV3)	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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-299-86	1000 mL in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/18/2010	

**Labeler** - Hy-Vee, Inc (006925671)

**Registrant** - Vi-Jon (790752542)

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(42507-299)

Revised: 1/2013

Hy-Vee, Inc