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.

--------

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
Cetylpyridinium chloride 0.07%

Purpose
Antigingivitis, Antiplaque

Use
helps control plaque that leads to gingivitis

Warnings
for this product

Stop use section
• 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
• 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, 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
299.005/299AK

**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

Compare to active ingredient in Crest Pro-Health rinse
1 L (33.8 FL OZ)
**Product Information**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:42507-299</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
<td></td>
</tr>
</tbody>
</table>

**Active Ingredient/Active Moiety**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)</td>
<td>CETYLPYRIDINIUM CHLORIDE</td>
<td>0.7 mg in 1 mL</td>
</tr>
</tbody>
</table>

**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER (UNII: 059QF0KOOR)</td>
<td></td>
</tr>
<tr>
<td>GLYCERIN (UNII: PDC6A3C0OX)</td>
<td></td>
</tr>
</tbody>
</table>
# POLOXAMER 188 (UNII: LQA7B6G8JG)
# SACCHARIN SODIUM (UNII: SB8ZUX40TY)
# PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
# SODIUM BENZOATE (UNII: OJ245FESEU)
# SUCRALOSE (UNII: 96K6UQ3ZD4)
# benzoic acid (UNII: 8SKN0B0MM)
# FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

## Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:42507-299-86</td>
<td>1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product</td>
<td>02/18/2010</td>
<td></td>
</tr>
</tbody>
</table>

## Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTC monograph not final</td>
<td>part356</td>
<td>02/18/2010</td>
<td></td>
</tr>
</tbody>
</table>

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

## Registrant
- Vi-Jon (790752542)

## Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vi-Jon</td>
<td></td>
<td>790752542</td>
<td>manufacture(42507-299)</td>
</tr>
</tbody>
</table>

Revised: 7/2018