

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.

Antiseptic Mouthrinse

299

Active Ingredient

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, sodium benzoate, sucralose, benzoic acid, blue 1

HyVee

Antiseptic Mouth Rinse Alcohol-Free

For better oral hygiene and fresher breath

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

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

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

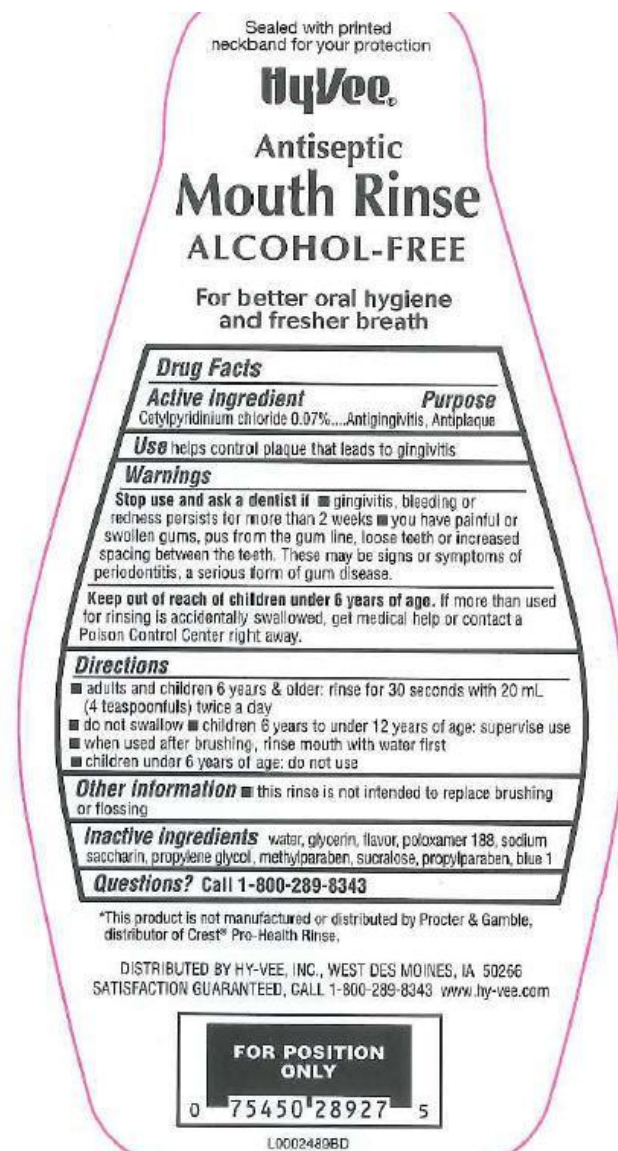
Zesty Mint

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)



ANTISEPTIC			
cetylpyridinium chloride 0.07% mouthwash			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42507-299
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: 059QF0K00R)			
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: 8SKN0B0MIM)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

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Packaging

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

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Marketing Information

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

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Labeler - Hy-Vee, Inc (006925671)

Registrant - Vi-Jon (790752542)

Establishment

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