

**MULTI-ACTION ANTISEPTIC- cetylpyridinium chloride rinse**  
**Greenbrier International, 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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**Assured 299.005/229AK-AL**

**claims**

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 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, sodium benzoate, sucralose, benzoic acid, blue 1

**disclaimer**

\*This product is not manufactured or distributed by Procter & Gamble, distributor of Crest Pro-Health Multi-Protection Alcohol Free Rinse - Refreshing Clean Mint

This rinse may cause temporary staining to the surface of teeth. This is not harmful and adequate brushing may prevent its occurrence.

**Adverse reactions**

DISTRIBUTED BY GREENBRIER INTERNATIONAL, INC.  
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

**principal display panel**

COMPARE TO ACTIVE INGREDIENT OF CREST PRO-HEALTH  
SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION  
ASSURED

FRESH MINT

ORAL

HEALTH

RINSE

MULTI-ACTION ALCOHOL-FREE ANTISEPTIC

ANTIGINGIVITIS/ANTIPLAQUE

Kills Germs That Cause Bad Breath, Plaque and the Gum Disease Gingivitis

Alcohol Free,

Freshens Breath

16.9 FL OZ (500 mL)

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ACTIVE INGREDIENT  
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NECKBAND FOR YOUR  
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**ASSURED**

**FRESH MINT**

# ORAL HEALTH RINSE

**MULTI-ACTION ALCOHOL-FREE  
ANTISEPTIC**

**ANTINGIVITIS / ANTIPLAQUE**

**Kills Germs That Cause  
Bad Breath, Plaque and  
the Gum Disease Gingivitis**

**Alcohol Free,  
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L0016413FA

**16.9 FL OZ (500 mL)**

## **MULTI-ACTION ANTISEPTIC**

cetylpyridinium chloride rinse

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:33992-0299
<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: 8SKN0B0MIM)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:33992-0299-7	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/09/2017	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part356	02/09/2017	

**Labeler** - Greenbrier International, Inc (610322518)**Registrant** - Vi-Jon (790752542)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Vi-Jon		790752542	manufacture(33992-0299)