

MULTI-ACTION ANTISEPTIC- cetylpyridinium chloride rinse
American Sales Company

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.

Multi-Action Alcohol-free antiseptic Mouth Rinse with CPC
299.005 299AK-AL

Sealed With Printed Neckband For Your Protection

Active ingredient

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

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 Proctor & Gamble, distributor of Crest Pro-Health Multi-Protection Alcohol Free Rinse - Refreshing Clean Mint

DISTRIBUTED BY:

Foodhold U.S.A., LLC

Landover, MD 20785

1-877-846-9949

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CAREONE

Compare to Crest Pro health Clean Mint

MULTI-ACTION

ANTISEPTIC ORAL RINSE

ANTINGIVITIS/ANTIPLAQUE

KILLS GERMS

ALCOHOL-FREE

VIVID MINT FLAVOR

HELPS PREVENT PLAQUE

HELPS PREVENT GINGIVITIS

FRESHENS BREATH

33.8 FL OZ (1.05 QT) 1 L



MULTI-ACTION ANTISEPTIC

cetylpyridinium chloride rinse

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:41520-299

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPIRIDINIUM - UNII:CUB7J10JV3)	CETYLPIRIDINIUM 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)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-299-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/25/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	04/25/2018	

Labeler - American Sales Company (809183973)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(41520-299)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(41520-299)

