

ANTISEPTIC- cetylpyridinium chloride mouthwash
Shopko Stores Operating

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.

Shopko 299.005 299AK AL Antiseptic Mouthrinse
299

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

To OPEN:

1. Remove Printed Tamper Evident Neckband
2. Squeeze both tabs at Base of cap while turning the cap until loose.

To CLOSE: Place cap back on bottle and turn cap until it clicks twice and feels secure.

Sealed with printed neckband for your protection

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

Manufactured by Vi-Jon, Inc.,

One Swan Drive., Smyrna, TN37167

For Shopko Stores Operating Co., LLC

www.shopko.com

For consumer questions call 1-888-593-0593

Shopko Satisfaction Guaranteed By Refund Or Exchange

principal display panel

SHOPKO

Compare to the active ingredients of Crest
Antiseptic Alcohol Free Oral Rinse Vivid Mint

Antigingivitis/Antiplaque Mouthrinse

Kills germs

Helps prevent plaque

Helps prevent gingivitis

Helps keep teeth feeling clean

Freshens breath

No burn of alcohol

33.8 FL OZ (1000 mL)



ANTISEPTIC

cetylpyridinium chloride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-299
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII: CUB7J10JV3)	CETYLPYRIDINIUM CHLORIDE	0.7 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C00X)	
POLOXAMER 188 (UNII: LQA7B6G8JG)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
Does not contain	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012-299-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/13/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/13/2009	

Labeler - Shopko Stores Operating (023252638)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(37012-299)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(37012-299)