

HEALTH- cetylpyridinium chloride mouthwash
DZA Brands LLC

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
299.005/299AK-AL

Claims

Healthy

Accents

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 & older: 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

Healthy Accents

For Better Oral Hygiene and Fresher Breath

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

DISTRIBUTED BY: DZA BRANDS, LLC

2110 Executive Drive

Salisbury, NC 28147

For product questions or concerns,

contact us at 1-866-322-2439

Please include UPC number and code from the package

principal display panel

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

healthy accents multi-action alcohol free antiseptic oral rinse

antigingivitis/antiplaque

- Kills germs
- Helps prevent plaque
- Helps prevent gingivitis
- Helps keep teeth feeling clean
- Freshens breath
- No burn of alcohol

compare to the ingredients in Crest Pro-Health Multi-Protection Alcohol Free Rinse- Refreshing Clean Mint*

1 L (33.8 FL OZ)



1L (33.8 FL OZ)

HEALTH

cetylpyridinium chloride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55316-942
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPIRIDINIUM - UNII:CUB7J0JV3)	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:55316-942-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	04/03/2015	

Labeler - DZA Brands LLC (090322194)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55316-942)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55316-942)

Revised: 6/2022

DZA Brands LLC