ANTISEPTIC- cetylpyridinium chloride mouthwash Liberty Procurement, 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 Mouthwash 299.005/299AL

Active ingredient

Cetylpyridinium chloride 0.07%

Purpose

Antigingivitis, Antiplaque

Use

helps control plaque that leads to gingivitis

Warnings

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 20mL (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

Safety Information

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

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

COREVLAUES

Antiseptic

MOUTHWASH

ANTIGINGIVITIS/ANTIPLAQUE ORAL RINSE

MULTI-ACTION

Distributed by

Liberty Procurement, Inc.

650 Liberty Ave.

Union, NJ 07083 USA

Visit us at www.facevalues.com

299.005/299AK

principal display panel

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

ALCOHOL FREE

COREVALUES

Compare to Crest Pro-Health Clean Mint Antiseptic MOUTHWASH*

ANTIGINGIVITIS/ANTIPLAQUE ORAL RINSE

MULTI-ACTION

- Kills germs
- Helps prevent plaque
- Helps prevent gingivits
- Freshens breath

Zesty Mint 1 L (33.8 FL OZ) SEALED WITH PRINTED NECK BAND FOR YOUR PROTECTION

ALCOHOL FREE

CORE VALUES™

Compare to Crest® Pro-Health Clean Mint*

Antiseptic MOUTHWASH

ANTIGINGIVITIS / ANTIPLAQUE ORAL RINSE

MULTI-ACTION

- Kills germs
- Helps prevent plaque
- Helps prevent gingivitis
- Freshens breath

Zesty Mint

1 L (33.8 FL OZ)

L0010124FE

ANTISEPTIC

cetylpyridinium chloride mouthwash

Product	Inform	ation
Product		ation

AN OTC DRUG Item Code	(Source)	NDC:63940-299
,	AN OTC DRUG Item Code	AN OTC DRUG Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name CETYLPYRIDINIUM CHLORIDE (UNII: D90M4SK49P) (CETYLPYRIDINIUM - UNII: CUB7JI0JV3) Basis of Strength CETYLPYRIDINIUM CETYLPYRIDINIUM 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: 85KN0B0MIM)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		

Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date
	1 NDC:63940-299-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/11/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Marketing E Date Date	
OTC monograph not final	part356	07/11/2016	

Labeler - Liberty Procurement, Inc (804085293)

Registrant - Vi-Jon, LLC (790752542)

Establishme	nt		
Name	Address	ID/FEI	Business Operations

Vi-Jon, LLC 790752542 manufacture(63940-299)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(63940-299)

Revised: 9/2023 Liberty Procurement, Inc