

ANTISEPTIC- cetylpyridinium chloride rinse
Perrigo Direct, 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.

Multi Action Alcohol Free Antiseptic Rinse w/CPC
299.005/299AK-AL

claims

GOODSENSE

Alcohol Free Antiseptic Oral Rinse

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

****Killed at least 99% of representative plaque organisms commonly associated with gingivitis in as little as 15 seconds**

Distributed by: Perrigo Direct, Inc.

Peachtree City, GA 30269

www.PerrigoDirect.com

1-888-593-0593

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principal display panel

GOODSENSE

Alcohol Free Antiseptic Oral Rinse

Antigingivitis/Antiplaque

Mint Flavor

Kills 99% of Germs for a healthier Mouth**

Helps prevent Plaque

Helps prevent gingivitis

Helps keep teeth feeling clean

Freshens Breath

No burn of alcohol

Compare to active ingredients of Crest Pro-Health Rinse*

1 LITER (33.8 FL OZ)



ANTISEPTIC

cetylpyridinium chloride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-299
Route of Administration	ORAL		

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:50804-299-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/20/1993	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/20/1993	

Labeler - Perrigo Direct, Inc (076059836)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(50804-299)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		088520668	manufacture(50804-299)