ANTISEPTIC- cetylpyridinium chloride mouthwash Wakefern Food Corp

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.

Antis eptic Mouthrins e 299

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 Contol Center right away.

Directions

- adults and children 6 years of age & 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

Sealed with printed neckband for your protection

For better oral hygiene and fresher breath

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

DISTRIBUTED BY

WAKEFERN FOOD CORP

5000 RIVERSIDE DRIVE

KEASBEY, NJ 08832

1-800-SHOPRITE

www.shoprite.com

299.005/299AK

principal display panel

Compare to active ingredient in Crest Pro-Health Rinse

ShopRite Antiseptic Oral Rinse

CPC Antigingivitis/Antiplaque

ALCOHOL FREE

- Kills germs
- Help prevent plaque
- Helps keep teeth feeling clean
- Freshen Breath
- No Burn of alcohol

ZESTY MINT

1L (33.8 FL OZ)





ANTISEPTIC

cetylpyridinium chloride mouthwash

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:41190-299

Route of Administration ORAL

Active Ingredient/Active Moiety

retive ingredient retive typical				
Ingredient Name	Basis of Strength	Strength		
CETYLPYRIDINIUM CHLORIDE (UNII: D9 O M4SK49 P) (CETYLPYRIDINIUM - UNII: CUB7JI0 JV3)	CETYLPYRIDINIUM CHLORIDE	0.7 mg in 1 mL		

Inactive Ingredients				
Ingredient Name	Strength			
water (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
POLOXAMER 188 (UNII: LQA7B6G8JG)				
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
sucralose (UNII: 96K6UQ3ZD4)				
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:41190-299- 86	$1000\ mL$ in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2011	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	07/08/2011		

Labeler - Wakefern Food Corp (069722418)

Registrant - Vi-Jon (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon		790752542	manufacture(41190-299)	

Revised: 5/2020 Wakefern Food Corp