

ANTINGIVITIS/ANTIPLAQUE- cetylpyridinium chloride mouthwash
The Kroger Co

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.

Alcohol-Free Gum Defense Mouthwash
D00.000/D00AA

Kroger

Smooth Mint

KILLS THE GERMS THAT CAUSE BAD BREATH

Active Ingredient

Cetylpyridinium Chloride 0.07%

Purpose

Antigingivitis, Antiplaque

Use

helps control plaque {bacteria} 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, zinc lactate, benzoic acid, sodium saccharin, sucralose, sodium benzoate, poloxamer 407, blue 1

Questions?

Call 1-800-632-6900

This may cause temporary staining to the surface of teeth.

This is not harmful, and adequate brushing may prevent its occurrence.

Crest Pro-Health is a registered trademark of the Procter & Gamble Co., Cincinnati, OH 45202. The Procter and Gamble Co. is not affiliated with the Kroger Co. or this product.

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OH 45202

QUESTIONS OR COMMENTS 1-800-632-6900 WWW.KROGER.COM

Principal Panel Display

COMPARE TO

CREST PRO-HEALTH GUM AND BREATH

PURIFY CPC ANTIGINGIVITIS/ANTIPLAQUE

ORAL RINSE SMOOTH MINT*

Kroger

Smooth Mint

GUM DEFENSE

ALCOHOL FREE MOUTHWASH

ANTIGINGIVITIS/ANTIPLAQUE

KILLS THE GERMS

THAT CAUSE BAD BREATH

CPC ANTIGINGIVITIS/ANTIPLAQUE ORAL RINSE

HELPS DEFEND AGAINST EARLY SIGNS OF GUM DISEASE

HELPS IMPROVE GUM HYGIENE
 SEALED WITH PRINTED NECKBAND
 FOR YOUR PROTECTION
 1 L (1 QT 1.8 FL OZ)
 33.8 FL OZ



ANTINGINGIVITIS/ANTIPLAQUE

cetylpyridinium chloride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59450-997
Route of Administration	Oral		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cetylpyridinium Chloride (UNII: D9OM4SK49P) (CETYLPIRIDINIUM - UNII:CUB7J10JV3)	Cetylpyridinium Chloride	0.7 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
glycerin (UNII: PDC6A3C0OX)	
zinc lactate (UNII: 2GXR25858Y)	
benzoic acid (UNII: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
sucralose (UNII: 96K6UQ3ZD4)	
sodium benzoate (UNII: OJ245FE5EU)	
poloxamer 407 (UNII: TUF2IVW3M2)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59450-997-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/22/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/22/2022	

Labeler - The Kroger Co (006999528)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(59450-997)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		088520668	manufacture(59450-997)

