

ANTIGINGIVITIS/ANTIPLAQUE- cetylpyridinium chloride mouthwash
Topco Associates LLC

Top Care D53.000/D53AA-AB
Powerful Fresh Mint Mouthwash

Tamper Evident Statement

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Claims & Disclaimer

QUALITY GUARANTEED

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[®] Intense Clean Mint Mouthwash.

**Kills at least 99% of many organisms commonly associated with bad breath in as little as 15 seconds.

Active Ingredient

Cetylpyridinium Chloride 0.05%

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
- 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, alcohol (15 wt%), propylene glycol, flavor, poloxamer 407, sucralose, benzoic acid, sodium benzoate, cinnamal, blue 1, yellow 6

Questions?

Call 1-888-423-0139

Adverse reaction

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ITASCA, IL 60143

©TOPCO VIJA1123 QUESTIONS? 1-888-423-0139

topcare@topco.com www.topcarebrand.com

Scan here for more information or call 1-888-423-0139

DSP-TN-21091 DSP-MO-20087

Principal Panel Display

COMPARE TO CREST[®] PRO-HEALTH[®] INTENSE CLEAN MINT MOUTHWASH*

TopCare[®] everyday

Powerful Fresh

Antigingivitis/Antiplaque

Mouthwash

FRESH MINT

- Kills 99% of many bad breath germs**
- Freshens your breath

- Helps prevent plaque and gingivitis

IMPORTANT: Read directions for proper use.

1 L (1.05 QT) 33.8 FL OZ



ANTINGINGIVITIS/ANTIPLAQUE

cetylpyridinium chloride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-953
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7J10JV3)		CETYLPYRIDINIUM CHLORIDE	0.5 mg in 1 mL	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)				
ALCOHOL (UNII: 3K9958V90M)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
POLOXAMER 407 (UNII: TUF21VW3M2)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
BENZOIC ACID (UNII: 8SKN0B0MIM)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
CINNAMALDEHYDE (UNII: SR60A3XG0F)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-953-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/18/2024	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M505G(a)(3)	04/18/2024		

Labeler - Topco Associates LLC (006935977)

Registrant - Nice-Pak Products, LLC (119091520)

Establishment			
Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(76162-953)