COLGATE TOTAL ULTRA FRESH- cetylpyridinium chloride rinse Colgate-Palmolive Company

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.

Colgate® Total Ultra Fresh

Drug Facts

Active ingredient

Cetylpyridinium Chloride 0.075%

Purpose

Antigingivitis/Antiplaque

Uses

- helps prevent and reduce plaque and gingivitis
- helps control plaque bacteria that contribute to the development of gingivitis, an early form of gum disease, and bleeding gums

Warnings

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 increasing 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 12 years of age and older	vigorously swish 20 mL of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse.
children 6 years to	

under 12 years of	supervise use
age	
children under 6	do not use
years of age	do not use

Other information

- this rinse is not intended to replace brushing or flossing
- store at 59°F to 77°F
- keep from freezing

Inactive ingredients

Water, Glycerin, Propylene Glycol, Sorbitol, Poloxamer 407, Flavor, Potassium Sorbate, Citric Acid, Sodium Saccharin, Charcoal Powder, Blue 1, Red 40, Yellow 5.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE CO.

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 1 L Bottle Label

ALCOHOL FREE

Colgate®

Antigingivitis Antiplaque Mouthwash

Total

WHOLE MOUTH HEALTH

ULTRA FRESH

PROVIDES AN INSTANT AND

LONG-LASTING FRESH FEELING

CETYLPYRIDINIUM CHLORIDE MOUTHWASH

ANTIBACTERIAL

Kills 99% of Bacteria Significantly Reduces Plaque Helps Prevent Gingivitis

10X LONGER LASTING COOL*

PEPPERMINT • CHARCOAL

33.8 FL OZ (1.05 QT) 1L

PS0028155



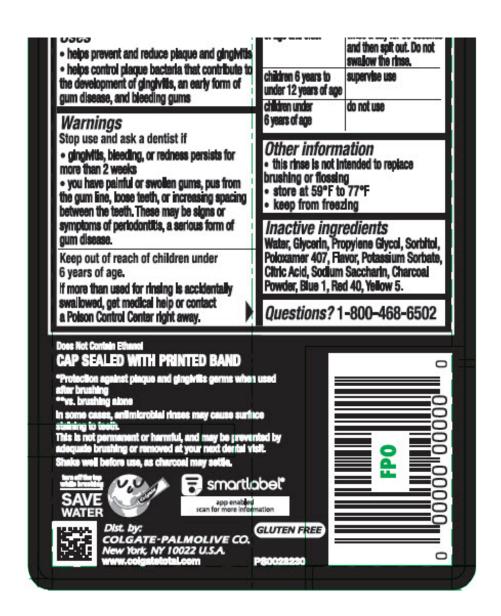
- · 12-HR protection against bacteria, even after eating and drinking
- Kills bacteria that cause bad breath, plaque and gingivitis
- To promote Healthy teeth and gums, use after brushing with Colgate Total® Advanced Toothpaste and Toothbrush

Drug Facts

Drug Facts (continued)

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COLGATE TOTAL ULTRA FRESH

cetylpyridinium chloride rinse

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:35000-735

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM -	CETYLPYRIDINIUM	15 mg
UNII:CUB7JI0JV3)	CHLORIDE	in 20 L

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics			
Color	BLACK	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

	Packaging					
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
:	NDC:35000-735-	1 L in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2022			

Marketing Information					
Marketing Category Application Number or Monograph Marketing Start Date Date					
OTC MONOGRAPH NOT FINAL	part356	01/01/2022			

Labeler - Colgate-Palmolive Company (001344381)

Revised: 1/2022 Colgate-Palmolive Company