COLGATE TOTAL ADVANCED GUM HEALTH MOUTHWASH- cetylpyridinium chloride rins e

Team Technologies, 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.

Colgate [®] Total _® Advanced Gum Health Mouthwash

Drug Facts

Active ingredient

Cetylpyridinium chloride 0.075%

Purpose

Antigingivitis/antiplaque

Uses

helps prevent and reduce plaque and gingivitis

Warnings

Ask a dentist if condition persists or worsens after regular use.

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	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	

Inactive ingredients

water, glycerin, propylene glycol, sorbitol, poloxamer 407, flavor, potassium sorbate, citric acid, sodium saccharin, sucralose, FD&C green no. 3

Other Information

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

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 500 mL Bottle Label

ALCOHOL FREE

 $Colgate^{\mathbb{R}}$

Antigingivitis Antiplaque Mouthwash

Total_®

GUM HEALTH

Advanced Gum Protection for 45% Stronger, Healthier Gums*

- 1. Fights plaque between teeth & along the gum line
- 2. Kills 99% of germs on contact
- 3. 12-hour protection against bacteria that cause gingivitis

CLEAN MINT

16.9 FL OZ (1.05 PT) 500 mL

P9903746





COLGATE TOTAL ADVANCED GUM HEALTH MOUTHWASH

cetylpyridinium chloride rinse

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67659-502(NDC:35000-723)		
Route of Administration	DENTAL				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CETYLPYRIDINIUM CHLO RIDE (UNII: D9 O M4S K49 P) (CETYLPYRIDINIUM - UNII: CUB7JI0 JV3)	CETYLPYRIDINIUM CHLORIDE	0.75 mg in 1 mL		

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

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

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

	Packaging				
:	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:67659-502-30	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/17/2016	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	0 3/0 1/20 15		

Labeler - Team Technologies, Inc (192339703)

Registrant - Team Technologies, Inc (192339703)

Establishment				
Name	Address	ID/FEI	Business Operations	
Team Technologies, Inc		079337800	repack(67659-502), relabel(67659-502)	

Revised: 5/2016 Team Technologies, Inc