

COLGATE TOTAL ADVANCED PRO-SHIELD SPEARMINT SURGE- cetylpyridinium chloride rinse

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 Pro-Shield™ Mouthwash Spearmint Surge™

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	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
children under 6 years of age	do not use

Inactive ingredients

water, glycerin, propylene glycol, sorbitol, poloxamer 407, flavor, potassium sorbate, sodium saccharin, citric acid, sucralose, FD&C green no. 3, FD&C yellow no. 6

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®

Antigingivitis/Antiplaque Mouthwash

Total®

ADVANCED

PRO-SHIELD™

12-HR Protection Against Germs*

- **KILLS 99% OF GERMS ON CONTACT**
- **SIGNIFICANTLY REDUCES PLAQUE**
- **HELPS PREVENT GINGIVITIS**
- **NO BURN OF ALCOHOL**
- **FRESHENS BREATH**

SPEARMINT SURGE™

16.9 FL OZ

(1.05 PT)

500 mL

P9892865



ADVANCED PRO-SHIELD™

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

<p>Drug Facts</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 50%;">Active ingredient</th> <th style="width: 50%;">Purpose</th> </tr> <tr> <td>Cetylpyridinium chloride 0.075%.....</td> <td>Antigingivitis/antiplaque</td> </tr> </table> <p>Uses helps prevent and reduce plaque and gingivitis</p> <p>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.</p> <p>Directions</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">adults and children 12 years of age and older</td> <td style="width: 50%;">rinse for 30 seconds with 20 mL (4 teaspoonfuls) twice a day. Do not swallow.</td> </tr> <tr> <td>children 6 years to under 12 years of age</td> <td>supervise use</td> </tr> <tr> <td>children under 6 years of age</td> <td>do not use</td> </tr> </table> <p>In some cases, antimicrobial rinses may cause surface staining to teeth. This is not permanent or harmful, and may be prevented by adequate brushing or removed at your next dental visit. CAP SEALED WITH PRINTED BAND *Results improve with continued twice daily use</p> <p style="font-size: small;">Dist. by: COLGATE-PALMOLIVE COMPANY New York, NY 10022 MADE IN U.S.A. www.colgatetotal.com</p>	Active ingredient	Purpose	Cetylpyridinium chloride 0.075%.....	Antigingivitis/antiplaque	adults and children 12 years of age and 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	children under 6 years of age	do not use	<p>Drug Facts (continued)</p> <p>Inactive ingredients water, glycerin, propylene glycol, sorbitol, poloxamer 407, flavor, potassium sorbate, sodium saccharin, citric acid, sucralose, FD&C green no. 3, FD&C yellow no. 6</p> <p>Other Information</p> <ul style="list-style-type: none"> • this rinse is not intended to replace brushing or flossing • store at 59°F to 77°F • keep from freezing <p>Questions? 1-800-468-6502</p> <div style="text-align: right;"> <p style="font-size: small;">P9892924 0 35000 67125 7</p> </div>
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COLGATE TOTAL ADVANCED PRO-SHIELD SPEARMINT SURGE

cetylpyridinium chloride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67659-501(NDC:35000-721)
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYL PYRIDINIUM - UNII: CUB7JI0JV3)	CETYL PYRIDINIUM CHLORIDE	15 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C00X)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

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:67659-501-30	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	05/06/2013	

Labeler - Team Technologies, Inc (192339703)

Registrant - Team Technologies, Inc (192339703)

Establishment			
Name	Address	ID/FEI	Business Operations
Team Technologies, Inc		079337800	repack(67659-501) , relabel(67659-501)