

COLGATE TOTAL 12 HR PRO-SHIELD SPEARMINT SURGE- 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™ 12 Hr Pro-Shield Spearmint Surge

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 age	supervise use
children under 6 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, sodium saccharin, citric acid, sucralose, FD&C green no. 3, FD&C yellow no. 6

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

Anti plaque Mouthwash

Total™

WHOLE MOUTH HEALTH

12 HR PROTECTION*

EVEN

AFTER

EATING & DRINKING

Kills 99% of Germs on Contact

Significantly Reduces Plaque

Helps Prevent Gingivitis

10X LONGER LASTING COOL**

SPEARMINT

33.8 FL OZ (1.05 QT) 1L

P9930420

ALCOHOL FREE

Colgate[®]
Antigingivitis Antiplaque Mouthwash



12 HR PROTECTION*
EVEN AFTER EATING & DRINKING

Kills 99% of Germs on Contact

Significantly Reduces Plaque

Helps Prevent Gingivitis

10X LONGER LASTING COOL**

SPEARMINT

33.8 FL OZ (1.05 QT) 1L

P9931420

- 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

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Does Not Contain Ethanol

CAP SEALED WITH PRINTED BAND

*Protection against plaque and gingivitis germs when used after brushing
**vs. brushing alone

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.

turn off the tap while brushing

SAVE WATER



smartlabel®

app enabled scan for more information

Dist. by:

COLGATE-PALMOLIVE CO.

New York, NY 10022 U.S.A.

www.colgatetotal.com

GLUTEN FREE

P9930421



COLGATE TOTAL 12 HR PRO-SHIELD SPEARMINT SURGE

cetylpyridinium chloride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-731
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

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

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)	
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:35000-731-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2015	
2	NDC:35000-731-84	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2015	
3	NDC:35000-731-16	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2015	
4	NDC:35000-731-33	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2015	
5	NDC:35000-731-50	1500 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	09/01/2015	

