COLGATE CAVITY PROTECTION FRESH MINT- sodium fluoride gel, dentifrice 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® Cavity Protection Fresh Mint

Drug Facts

Active ingredient

Sodium Fluoride 0.24% (0.15% w/v fluoride ion)

Purpose

Anticavity

Use

helps protect against cavities

Warnings

Keep out of reach of children under 6 years of age.

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 2 years of	brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician	
children 2 to 6 years	use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)	
children under 2 years	ask a dentist or physician	

Inactive ingredients

Sorbitol, Water, Hydrated Silica, Sodium Lauryl Sulfate, Flavor, PEG-12, Cellulose Gum, Sodium Saccharin, Blue 1, Yellow 5.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE CO.

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 113 g Tube Label

 $\mathsf{Colgate}^{\circledR}$

ages 8+

Fluoride

Toothpaste

FRESH MINT flavor

Clinically Proven Cavity and Enamel Protection

Toothpaste

NET WT 4.0 OZ (113 g)



COLGATE CAVITY PROTECTION FRESH MINT

sodium fluoride gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-914
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8 ZYQ 1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	1.1 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
SORBITOL (UNII: 506T60A25R)	680 mg in 1 g	
WATER (UNII: 059QF0KO0R)		
HYDRATED SILICA (UNII: Y6O7T4G8P9)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)		
CARBO XYMETHYLCELLULO SE SO DIUM, UNSPECIFIED FORM (UNII: K679 OBS 311)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		

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

	Packaging				
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:35000-914-69	113 g in 1 TUBE; Type 0: Not a Combination Product	08/05/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	08/05/2019	

Labeler - Colgate-Palmolive Company (001344381)

Revised: 12/2019 Colgate-Palmolive Company