COLGATE CAVITY PROTECTION- 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 Gel

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

of age and older	brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician
	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, FD&C blue no. 1, FD&C yellow no. 5

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 119 g Tube Label

Cavity

Protection Gel

Helps Strengthen Teeth

Colgate® Fluoride Toothpaste

ADA

Accepted American Dental Association

Toothpaste

NET WT 4.2 OZ (119 g)



COLGATE CAVITY PROTECTION

sodium fluoride gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-953
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (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)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
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					
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:35000-953-71	119 g in 1 TUBE; Type 0: Not a Combination Product	04/06/2014		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	04/06/2014	

Labeler - Colgate-Palmolive Company (001344381)

Revised: 12/2019 Colgate-Palmolive Company