

COLGATE CAVITY PROTECTION- sodium fluoride gel, dentifrice
Mission Hills S.A de C.V

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 toothpaste Fluoride Toothpaste

Drug Facts

Active ingredient

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

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 age and older	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, PEG-12, flavor, cellulose gum, sodium saccharin, FD&C red no. 40

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:65954-559
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	1.1 mg in 1 g	
Inactive Ingredients				
Ingredient Name		Strength		
SORBITOL (UNII: 506T60A25R)		339.99 mg in 1 g		
WATER (UNII: 059QF0KO0R)				
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
Product Characteristics				
Color	RED	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65954-559-71	147 g in 1 TUBE		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL		part355	02/25/2012	

Labeler - Mission Hills S.A de C.V (812312122)