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	brush teeth thoroughly, preferably after	
years of age and	each meal or at least twice a day, or as	
older	directed by a dentist or physician	
	use only a pea sized amount and	
children 2 to 6 years	supervise child's brushing and rinsing	
-	(to minimize swallowing)	
children under 2	ask a doutist or physician	
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 LABEL	Item Code (Source)	NDC:65954-559
Route of Administration	DENTAL	DEA Sche dule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (FLUORIDE ION)	FLUORIDE ION	1.1 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
SORBITOL	339.99 mg in 1 g		
WATER			
HYDRATED SILICA			
SODIUM LAURYL SULFATE			
POLYETHYLENE GLYCOL 600			
CARBO XYMETHYL CELLULO SE SODIUM			
SACCHARIN SO DIUM			
FD&C RED NO. 40			

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)

Revised: 1/2013 Mission Hills S.A de C.V