COLGATE MAX FRESH COOL 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® Max Fresh® Cool Mint 4.6oz 2in1 Fluoride Toothpaste

Drug Facts

Active ingredient

Sodium fluoride 0.24% (0.14% 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 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, PEG-12, sodium lauryl sulfate, flavor, tetrasodium pyrophosphate, xanthan gum, cocamidopropyl betaine, sodium saccharin, methylcellulose, FD&C blue no. 1

Questions?

1-800-468-6502

Dist by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 130 g Bottle Label

WITH WHITENING

MaxFresh[®]

WITH MINI

BREATH STRIPS

Colgate[®]

Anticavity Fluoride Toothpaste

Bursting with Freshness that Lasts for Hours!

COOL MINT

NET WT 4.6 OZ (130 g)





COLGATE MAX FRESH COOL MINT

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-947
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)	665.38 mg in 1 g		
WATER (UNII: 059QF0KO0R)			
HYDRATED SILICA (UNII: Y6O7T4G8P9)			
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
SO DIUM PYRO PHO SPHATE (UNII: O352864B8Z)			
XANTHAN GUM (UNII: TTV12P4NEE)			
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
METHYLCELLULOSE (100 MPA.S) (UNII: 4GFU244C4J)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			

Product Characteristics			
Color	BLUE	Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

l	Packaging				
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 N	NDC:35000-947-81	130 g in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2008	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	04/06/2008	

Labeler - Colgate-Palmolive Company (001344381)

Revised: 12/2019 Colgate-Palmolive Company