# COLGATE MAX FRESH COOL MINT- 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.

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## Colgate<sup>®</sup> Max Fresh<sup>®</sup> Cool Mint Fluoride Toothpaste

**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**

veers 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, PEG-12, sodium lauryl sulfate, flavor, cellulose gum, tetrasodium pyrophosphate, cocamidopropyl betaine, sodium saccharin, methylcellulose, FD&C blue no. 1

#### Questions or comments?

Call toll-free 1-800-468-6502

Dist. by:

**COLGATE-PALMOLIVE** COMPANY

New York, NY 10022

**Bursting with Freshness That Lasts for Hours** 

Colgate<sup>®</sup> Fluoride Toothpaste

**MaxFresh**®

WITH

MINI BREATH STRIPS

**WHITENING** 

**COOL MINT** 

NET WT 6.0 OZ (170 g)











## COLGATE MAX FRESH COOL MINT

sodium fluoride gel, dentifrice

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:65954-014	
Route of Administration	DENTAL	DEA Schedule		

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	564.38 mg in 1 g			
WATER				
HYDRATED SILICA				
POLYETHYLENE GLYCOL 600				
SODIUM LAURYL SULFATE				
CARBO XYMETHYLCELLULO SE SODIUM				
SO DIUM PYRO PHO SPHATE				
COCAMIDO PRO PYL BETAINE				
SACCHARIN SO DIUM				
PO WDERED CELLULOSE				
FD&C BLUE NO. 1				

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

Packagi	Packaging				
# I1	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:659	954-014-60	1 in 1 CARTON			
1		170 g in 1 TUBE			

2	NDC:65954-014-01	1 in 1 CARTON	
2		28.3 g in 1 TUBE	
3	NDC:65954-014-75	1 in 1 CARTON	
3		79 g in 1 TUBE	
4	NDC:65954-014-78	1 in 1 CARTON	
4		221 g in 1 TUBE	
5	NDC:65954-014-99	1 in 1 CARTON	
5		53 g in 1 TUBE	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	08/01/2011	

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

Revised: 7/2013 Mission Hills S.A de C.V