COLGATE MAX CLEAN EFFERVESCENT 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.

Colgate[®] Max Clean™ Efferves cent mint™ Fluoride Toothpas te

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	use only a pea sized amount and supervise child's brushing and rinsing (to
years	minimize swallowing)
children under 2	ask a dentist or physician
years	ask a definist of physician

Inactive ingredients

water, sorbitol, hydrated silica, PEG-12, poloxamer 407, sodium lauryl sulfate, flavor, xanthan gum, cocamidopropyl betaine, tetrasodium pyrophosphate, sodium saccharin, methylcellulose, mica, titanium dioxide, FD&C blue no. 1

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 170 g Tube Label

 $Colgate^{\mathbb{R}}$

Anticavity Fluoride Toothpaste

30% More Foam*

Cleans Tough to Reach Spaces

NET WT 6.0 OZ (170 g)

WITH WHITENING

MaxCleanTM

SMARTFOAM[®]

EFFERVESCENT MINTTM



COLGATE MAX CLEAN EFFERVESCENT MINT sodium fluoride gel, dentifrice Product Information Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:65954-381 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	347 mg in 1 g		
WATER			
HYDRATED SILICA			
POLYETHYLENE GLYCOL 600			
POLOXAMER 407			
SODIUM LAURYL SULFATE			
XANTHAN GUM			
COCAMIDO PRO PYL BETAINE			
SO DIUM PYRO PHO SPHATE			
MICA			
TITANIUM DIO XIDE			
SACCHARIN SO DIUM			
METHYLCELLULOSE (400 MPA.S)			
FD&C BLUE NO. 1			

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

Packaging				
# Item Co	de Package Descri	iption Marketing Start Da	nte Marketing End Date	
1 NDC:65954-381-0	1 in 1 CARTON			
1	28.3 g in 1 TUBE			
2 NDC:65954-381-6	1 in 1 CARTON			
2	170 g in 1 TUBE			
3 NDC:65954-381-8	1 in 1 CARTON			
3	204 g in 1 TUBE			
4 NDC:65954-381-3	78 1 in 1 CARTON			
4	221 g in 1 TUBE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	03/18/2011	

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

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