# COLGATE MAX FRESH CLEAN 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.

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# Colgate® Max Fresh® Clean 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**

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, cellulose gum, tetrasodium pyrophosphate, cocamidopropyl betaine, sodium saccharin, methylcellulose, FD&C blue no. 1, FD&C yellow no. 5

## **Questions?**

#### 1-800-468-6502

Dist. by:

**COLGATE-PALMOLIVE** COMPANY

New York, NY 10022

# PRINCIPAL DISPLAY PANEL - 170 g Tube Carton

**Colgate**®

**Anticavity** 

Fluoride Toothpaste

**Bursting with Freshness That Lasts for Hours!** 

WITH WHITENING

maxFresh®

WITH

**MINI BREATH STRIPS** 

**CLEAN MINT** 

NET WT 6.0 OZ (170 g)



#### **COLGATE MAX FRESH CLEAN MINT**

sodium fluoride gel, dentifrice

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:35000-902

Route of Administration DENTAL

#### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) | SODIUM FLUORIDE | 2.4 mg in 1 g

#### **Inactive Ingredients**

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	564.38 mg in 1 g
WATER (UNII: 059QF0KO0R)	

**HYDRATED SILICA** (UNII: Y6O7T4G8P9)

POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics			
Color	GREEN	Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-902- 60	1 in 1 CARTON	08/01/2011	
1		170 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-902- 78	1 in 1 CARTON	08/01/2011	
2		221 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:35000-902- 63	1 in 1 CARTON	03/28/2022	
3		178 g in 1 TUBE; Type 0: Not a Combination Product		

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

# **Labeler -** Colgate-Palmolive Company (001344381)

Establishment			
Name	Address	ID/FEI	Business Operations
Mission Hills, S.A. de C.V.		812312122	ANALYSIS(35000-902), MANUFACTURE(35000-902), PACK(35000-902), LABEL(35000-902)