

**COLGATE MAXFRESH FRESH 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® Max Fresh® One Direction 4.6 oz 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, tetrasodium pyrophosphate, flavor, cocamidopropyl betaine, sodium saccharin, cellulose gum, xanthan gum, 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 - 130 g Bottle Label**

1D™

Colgate®

Fluoride Toothpaste

1D™

Fresh Mint

NET WT 4.6 OZ (130g) LIQUID GEL

**Colgate® MaxFresh®**

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Remove tab with arrows to open cap.

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DATE CODE AREA

Dist. by: COLGATE-PALMOLIVE COMPANY  
New York, NY 10022

www.colgate.com  
Made in Mexico

NET WT 4.6 OZ (130g) LIQUID GEL

**COLGATE MAXFRESH FRESH MINT**

sodium fluoride gel, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG LABEL	<b>Item Code (Source)</b>	NDC:659 54-0 10
<b>Route of Administration</b>	DENTAL	<b>DEA Schedule</b>	

**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	670 mg in 1 g
WATER	
HYDRATED SILICA	
POLYETHYLENE GLYCOL 600	
SODIUM LAURYL SULFATE	
SODIUM PYROPHOSPHATE	
COCAMIDOPROPYL BETAINE	
SACCHARIN SODIUM	
CARBOXYMETHYLCELLULOSE SODIUM	
XANTHAN GUM	
MICA	
TITANIUM DIOXIDE	
FD&C BLUE NO. 1	

**Product Characteristics**

Color	BLUE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65954-010-81	130 g in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	01/08/2013	

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

Revised: 2/2014

Mission Hills S.A de C.V