# 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<sup>®</sup> Max Fresh<sup>®</sup> 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	brush teeth thoroughly, preferably	
children 2	after each meal or at least twice a	
years of age	day, or as directed by a dentist or	
and older	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

#### PRINCIPAL DISPLAY PANEL - 130 g Bottle Label

1D<sub>TM</sub>

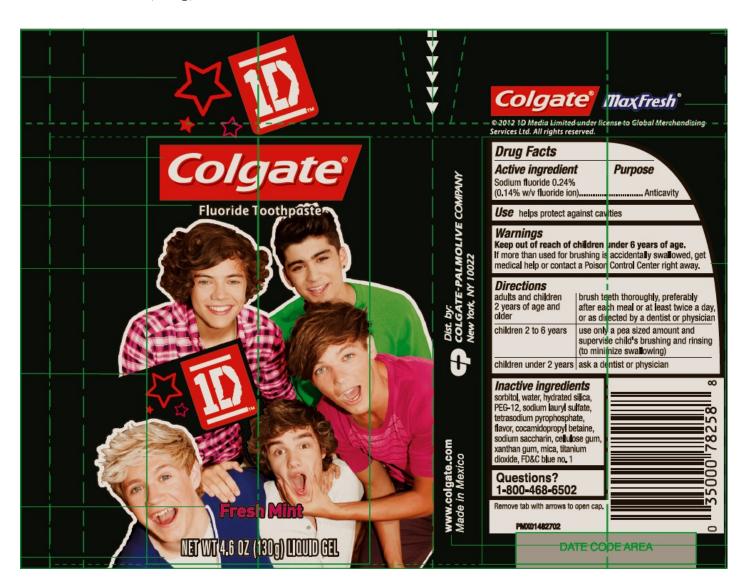
Colgate<sup>®</sup>

Fluoride Toothpaste

 $1D_{TM}$ 

Fresh Mint

NET WT 4.6 OZ (130g) LIQUID GEL



### **COLGATE MAXFRESH FRESH MINT**

sodium fluoride gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:65954-010
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	670 mg in 1 g
WATER	
HYDRATED SILICA	
POLYETHYLENE GLYCOL 600	
SODIUM LAURYL SULFATE	
SO DIUM PYRO PHO SPHATE	
CO CAMIDO PRO PYL BETAINE	
SACCHARIN SO DIUM	
CARBO XYMETHYLCELLULO SE SODIUM	
XANTHAN GUM	
MICA	
TITANIUM DIO XIDE	
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