

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.

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65954-010
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	670 mg in 1 g
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

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