

COLGATE LUMINOUS CRYSTAL FLUORIDE- 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®
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 the 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, mica, titanium dioxide, FD&C blue no.1

Questions or comments?

Call toll-free **1-800-468-6502**

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

Made in Mexico

www.colgateluminous.com

PRINCIPAL DISPLAY PANEL - 113 g carton

Colgate®

Fluoride Toothpaste

ADA

Accepted

American

Dental

Association®

NET WT 4.0 OZ (113 g)

LUMINOUS

Enamel Strengthening

CRYSTAL CLEAN MINT™

33%

FREE

3.0oz + 1.0oz

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Fluoride Toothpaste



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Drug Facts (continued)

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"The ADA Council on Scientific Affairs' Acceptance of Colgate Luminous Fluoride Toothpaste is based on its finding that the product is effective in helping to prevent and reduce tooth decay, and to whiten teeth by removing surface stains, when used as directed."

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LUMINOUS®

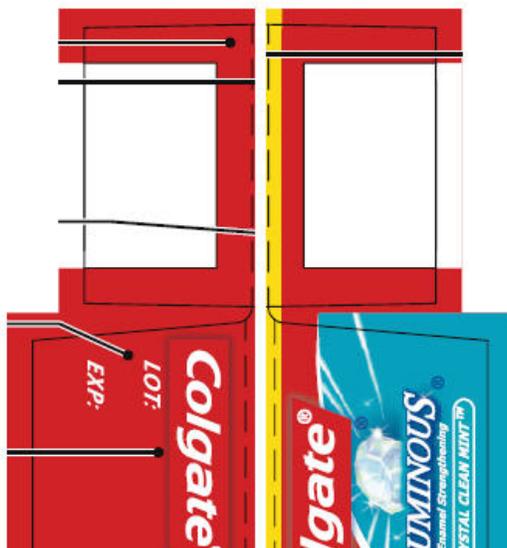
Enamel Strengthening

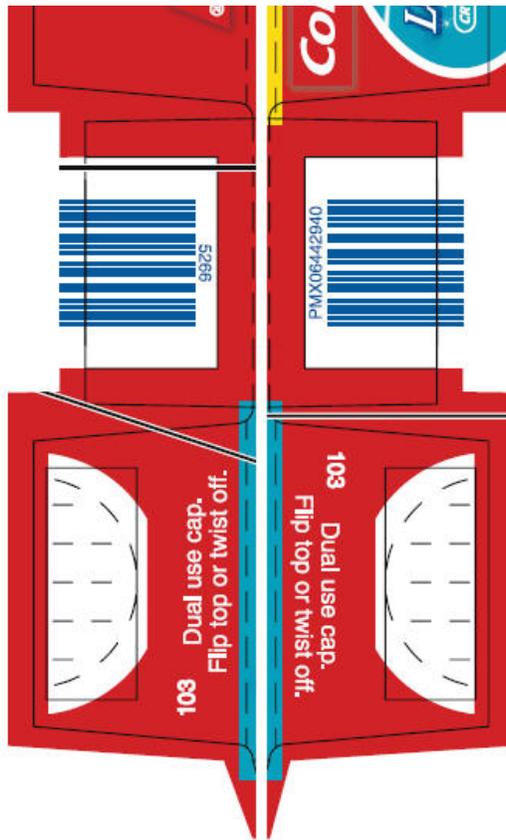
For Stronger, Shinier, Whiter Teeth
Reinforces enamel layers by rebuilding the weak spots
Safely lifts off yellowing surface stains to whiten teeth

WHITENS TEETH FRESHENS BREATH FIGHTS CAVITIES

Experience the cool of
CRYSTAL CLEAN MINT™

Colgate®





COLGATE LUMINOUS CRYSTAL FLUORIDE

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65954-022
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)	564.38 mg in 1 g
WATER (UNII: 059QF0K00R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
MICA (UNII: V8A1AW0880)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	BLUE (sky blue)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65954-022-69	1 in 1 CARTON		
1		113 g in 1 TUBE		
2	NDC:65954-022-64	1 in 1 CARTON		
2		181 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/03/2009	

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

Revised: 4/2013

Mission Hills S.A. de C.V.