

COLGATE MAX FRESH COOL 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® Cool Mint 4.6oz 2in1 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, flavor, tetrasodium pyrophosphate, xanthan gum, cocamidopropyl betaine, sodium saccharin, methylcellulose, 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

WITH WHITENING

MaxFresh®

WITH

MINI

BREATH STRIPS

Colgate®

Anticavity Fluoride Toothpaste

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

COOL

MINT

NET WT 4.6 OZ (130 g)

WITH WHITENING

MaxFresh

WITH **MINI BREATH STRIPS**

Colgate[®]
Anticavity
Fluoride Toothpaste

Bursting with
Freshness that
Lasts for Hours!

COOL
MINT



NET WT 4.6 OZ (130 g)

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



www.colgate.com/maxfresh
Made in Mexico

Drug Facts

Active ingredient

Sodium fluoride 0.24%

(0.14% w/v fluoride ion)..... Anticavity

Purpose

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

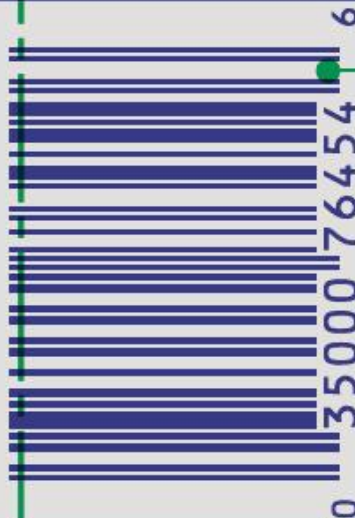
sorbitol, water, hydrated silica,
PEG-12, sodium lauryl sulfate,
flavor, tetrasodium
pyrophosphate, xanthan gum,
cocamidopropyl betaine, sodium
saccharin, methylcellulose,
FD&C blue no. 1

Questions?

1-800-468-6502

Remove tab with arrows to open cap.

PMX01482174



DATE CODE AREA

COLGATE MAX FRESH COOL MINT

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65954-564
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)	665.38 mg in 1 g
WATER (UNII: 059QF0K00R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
XANTHAN GUM (UNII: TTV12P4NEE)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYLCELLULOSE (100 MPA.S) (UNII: 4GFU244C4J)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65954-564-81	130 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	04/06/2008	

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