

COLGATE MAX FRESH INTENSE- sodium fluoride paste, 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®

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 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, zinc oxide, methylcellulose, FD&C blue no. 1, D&C red no. 33

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY
New York, NY 1002

PRINCIPAL DISPLAY PANEL - 170 g Tube Carton

Colgate®
Anticavity Fluoride Toothpaste
NEW INTENSE FRESHNESS

Max Fresh®
WITH
GERM-FIGHTING STRIPS

Removes **90%** of
Odor Causing Bacteria!*

INTENSE MINT WITH WHITENING

NET WT 6.0 OZ (170 g)



COLGATE MAX FRESH INTENSE

sodium fluoride paste, dentifrice

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:65954-554

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)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
METHYLCELLULOSE (25 MPA.S) (UNII: BI55GG2WLI)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

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:65954-554-60	1 in 1 CARTON		
1		170 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	12/08/2011	

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