COLGATE OPTIC WHITE COOL MILD MINT-sodium monofluorophosphate 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® Optic White® Cool Mild Mint Fluoride Toothpaste 5.5OZ

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76% (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

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
	use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)
children under 2 years	as a dentist or physician

Inactive ingredients

calcium pyrophosphate, propylene glycol, PEG/PPG 116/66 copolymer, PEG-12, glycerin, PVP, flavor, sodium lauryl sulfate, tetrasodium pyrophosphate, silica, hydrogen peroxide, sodium saccharin, phosphoric acid, sucralose, butylated hydroxytoluene, water

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 156 g Tube Carton Label

Colgate[®]

WHITER TEETH IN ONE WEEK

OPTIC

 $\textbf{WHITE}_{\circledR}$

DAILY ANTICAVITY FLUORIDE TOOTHPASTE | ENAMEL SAFE

NET WT 5.5 OZ (156 g)

COOL MILD MINT



WHITER TEETH IN ONE WEEK

DAILY ANTICAVITY FLUORIDE TOOTHPASTE | ENAMEL SAFE

COOL MILD MINT

OPTIC WHITE.



Colgate

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COOL MILD MINT

DAILY ANTICAVITY FLUORIDE TOOTH PASTE | ENAMEL SAFE

NET WT 5.5 OZ (156 g)

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Drug Facts (continued)

Directions

Purpose

adults and children 2 years of age and older bush teeth thoroughly, preferably after each meal or at least twice a 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

0.76% (0.15% w/v fluoride ion) Use helps protect against cavities

Drug Facts

Active ingredient

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.

Inactive ingredients calcium pyrophosphate, propylene glycol, PEG/PPG 116/66 copolymer, PEG-12, glycerin, PVP, flavor, sodium lauryl sulfate, tetrasodium pyrophosphate, silica, hydrogen peroxide, sodium saccharin, phosphoric acid, sucralose, butylated

Questions? 1-800-468-6502



WHITER TEETH IN ONE WEEK, HIGH-IMPACT WHITENING FORMULA.

Colgate

WHITE.



This daily toothpaste has a unique high-impact whitening formula.

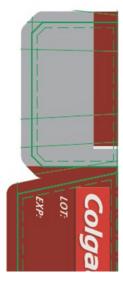


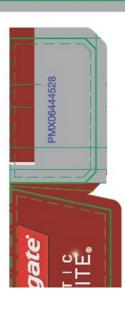
With regular use, it removes stains ordinary toothpastes don't.

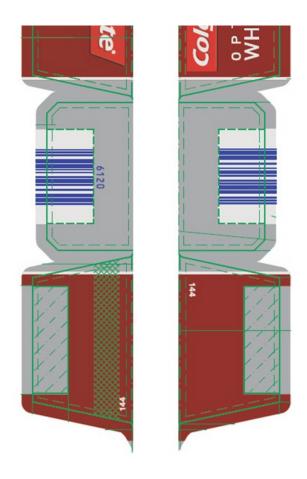


Whiter teeth start in 1 week. For best results, use as directed for 4 weeks.

BRUSH REGULARLY WITH COLGATE® OPTIC WHITE® TOOTHPASTE AND COLGATE® 360°® OPTIC WHITE® TOOTHBRUSH FOR A WHITER SMILE.







COLGATE OPTIC WHITE COOL MILD MINT

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65954-560
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	1 mg in 1 g	

Inactive Ingredients				
Ingredient Name	Strength			
CALCIUM PYRO PHO SPHATE (UNII: X69 NU20 D19)	351.1 mg in 1 g			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PEG/PPG-116/66 COPOLYMER (UNII: JPOCK963E0)				
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
PO VIDO NE K15 (UNII: E54VE15114)				
SODIUM LAURYL SULFATE (UNII: 368 GB5141J)				
SO DIUM PYRO PHO SPHATE (UNII: O352864B8Z)				

SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
HYDROGEN PERO XIDE (UNII: BBX060AN9V)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PHO SPHO RIC ACID (UNII: E4GA8884NN)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:65954-560-26	1 in 1 CARTON			
1		156 g in 1 TUBE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	0 1/0 2/20 13	

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

Revised: 1/2013 Mission Hills S.A de C.V