

COLGATE OPTIC WHITE SPARKLING 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™ Sparkling Mint® Fluoride Toothpaste

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

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

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 - 113 g Tube Carton

Colgate®

WHITER TEETH IN 1 WEEK

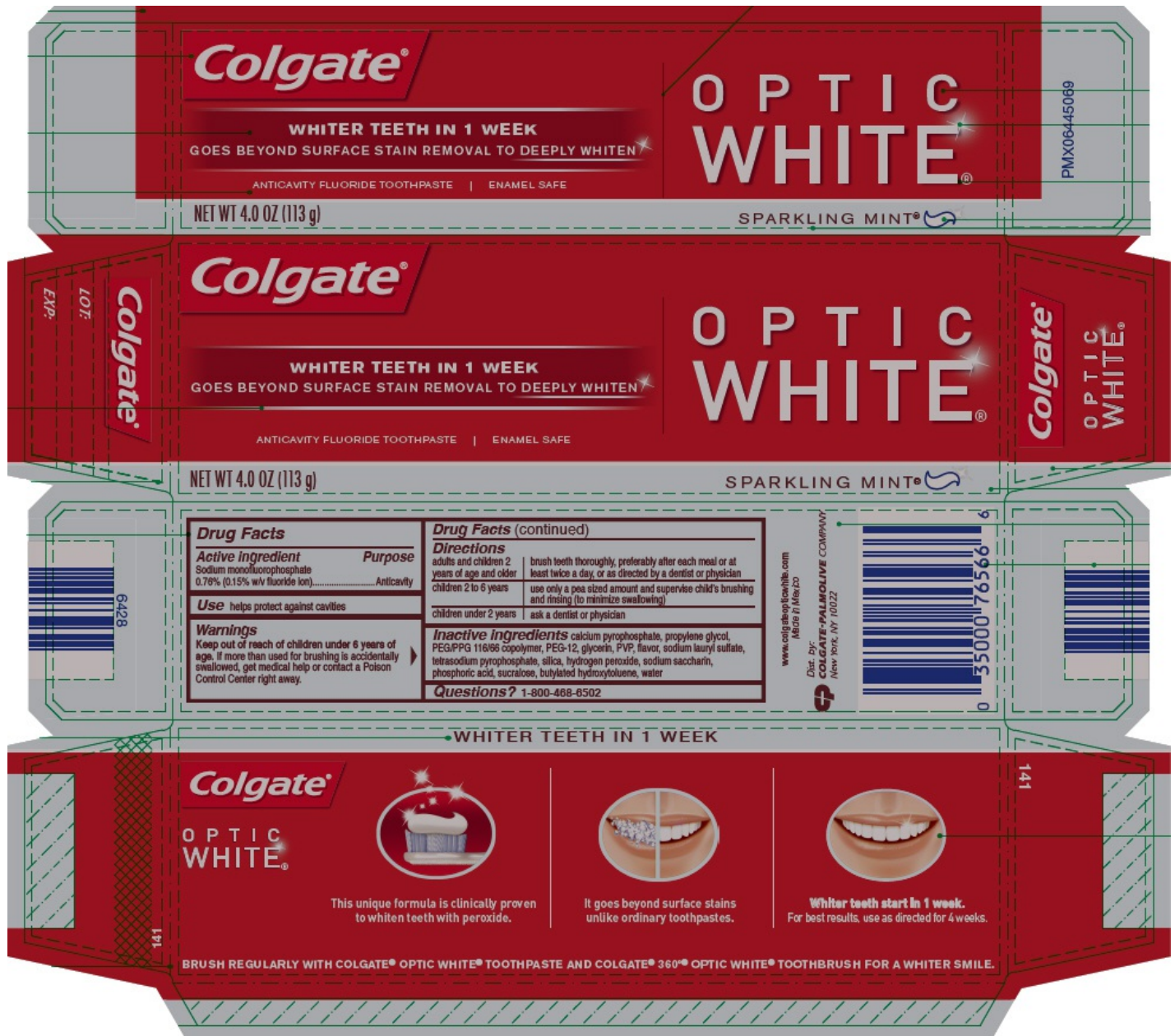
GOES BEYOND SURFACE STAIN REMOVAL TO DEEPLY WHITEN

ANTICAVITY FLUORIDE TOOTHPASTE | ENAMEL SAFE

**OPTIC
WHITE®**

NET WT 4.0 OZ (113 g)

SPARKLING MINT®



COLGATE OPTIC WHITE SPARKLING MINT

sodium monofluorophosphate paste, dentifrice

Product Information					
Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:65954-552
Route of Administration		DENTAL			
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Strength	Strength	
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)			FLUORIDE ION	1 mg in 1 g	
Inactive Ingredients					
Ingredient Name			Strength		
CALCIUM PYROPHOSPHATE (UNII: X69NU20D19)			351.1 mg in 1 g		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)					
PEG/PPG-116/66 COPOLYMER (UNII: JP0CK963E0)					
GLYCERIN (UNII: PDC6A3C0OX)					
POVIDONE K15 (UNII: E54VE15114)					
SODIUM LAURYL SULFATE (UNII: 368GB5141J)					
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)					
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)					
HYDROGEN PEROXIDE (UNII: BBX060AN9V)					
SACCHARIN SODIUM (UNII: SB8ZUX40TY)					
PHOSPHORIC ACID (UNII: E4GA8884NN)					
SUCRALOSE (UNII: 96K6UQ3ZD4)					
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)					
WATER (UNII: 059QF0KO0R)					
Product Characteristics					
Color		WHITE	Score		
Shape			Size		
Flavor		MINT	Imprint Code		
Contains					
Packaging					
#	Item Code	Package Description	Marketing Start Date		Marketing End Date
1	NDC:65954-552-69	1 in 1 CARTON			
1		113 g in 1 TUBE			
2	NDC:65954-552-26	1 in 1 CARTON			
2		156 g in 1 TUBE			
3	NDC:65954-552-97	1 in 1 CARTON			
3		198 g in 1 TUBE			
4	NDC:65954-552-98	1 in 1 CARTON			
4		62 g in 1 TUBE			
5	NDC:65954-552-20	1 in 1 CARTON			
5		24 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)

Revised: 10/2013

Mission Hills S.A de C.V