

COLGATE OPTIC WHITE BEAUTY RADIANT- 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 Beauty™ Radiant™ Toothpaste

Active ingredient

Sodium monofluorophosphate 1.14% (0.19% 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 6 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 6 to 12 years: instruct in good brushing and rinsing habits (to minimize swallowing)
- children under 6 years: do not use unless directed by a dentist or physician

Inactive ingredients

propylene glycol, calcium pyrophosphate, PVP, PEG/PPG-116/66 copolymer, PEG-12, glycerin, flavor, hydrogen peroxide, sodium lauryl sulfate, silica, tetrasodium pyrophosphate, disodium pyrophosphate, sodium saccharin, zinc oxide, citric acid, sucralose, BHT

Some people may experience tooth sensitivity or gum discomfort when using whitening products. This discomfort is temporary and not harmful. If you experience more than mild tooth sensitivity, stop use and consult your dentist.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE CO.

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 85 g Tube Label

RADIANT™

WHITENS INSIDE & OUT
FOR A RADIANT SMILE

Colgate®

**OPTIC
WHITE
BEAUTY™**

ANTICAVITY FLUORIDE TOOTHPASTE
ENAMEL SAFE
ICY MINT

NET WT 3.0 OZ (85 g)

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480902 951959 7275

SAVE WATER
www.djets.com/savewater

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New York, NY 10022 U.S.A.

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www.colgateopticwhite.com

COLGATE OPTIC WHITE BEAUTY RADIANT

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65954-385
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	392.5 mg in 1 g
CALCIUM PYROPHOSPHATE (UNII: X69NU20D19)	
POVIDONE K15 (UNII: E54VE15114)	
PEG/PPG-116/66 COPOLYMER (UNII: JP0CK963E0)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SODIUM ACID PYROPHOSPHATE (UNII: H5WVD9LZUD)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

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:65954-385-63	85 g in 1 TUBE; Type 0: Not a Combination Product	10/17/2016	
2	NDC:65954-385-16	1 in 1 CARTON	10/17/2016	
2		21.2 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	10/17/2016	

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