

**COLGATE OPTIC WHITE RENEWAL ENAMEL STRENGTH- sodium
monofluorophosphate paste, dentifrice
Colgate-Palmolive Company**

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® Renewal Enamel Strength

Drug Facts

Active ingredient

Sodium Monofluorophosphate 1.14% (0.18% 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	use only a pea sized amount and supervise child's brushing and rinsing (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, Hydrogen Peroxide, Flavor, Sodium Lauryl Sulfate, Tetrasodium Pyrophosphate, Sodium Saccharin, Disodium Pyrophosphate, Silica, Sucralose, BHT.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY
New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 85 g Tube Carton

Colgate®

Anticavity Fluoride Toothpaste

NEW

OPTIC

WHITE®

RENEWAL

REMOVES

10 YEARS OF

YELLOW STAINS*

HYDROGEN

3%

PEROXIDE

ENAMEL STRENGTH

NET WT 3.0 OZ (85 g)

ENAMEL SAFE



COLGATE OPTIC WHITE RENEWAL ENAMEL STRENGTH

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-980
Route of Administration	DENTAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	1.5 mg in 1 g	
Inactive Ingredients				
Ingredient Name		Strength		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		527.8 mg in 1 g		
CALCIUM PYROPHOSPHATE (UNII: X69NU20D19)				
POVIDONE K15 (UNII: E54VE15114)				
PEG/PPG-116/66 COPOLYMER (UNII: JP0CK963E0)				
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SODIUM ACID PYROPHOSPHATE (UNII: H5WVD9LZUD)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
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:35000-980-63	1 in 1 CARTON	11/04/2019	
1		85 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-980-60	2 in 1 CARTON	12/10/2019	
2		85 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	11/04/2019	

Labeler - Colgate-Palmolive Company (001344381)