

**COLGATE OPTIC WHITE PRO SERIES STAIN PREVENTION- 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.*

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**Colgate® Optic White® Pro Series Stain Prevention**

**Active ingredients**

Sodium Monofluorophosphate 0.76% (0.13% 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**

Poloxamer 105, PVP, Calcium Pyrophosphate, PEG/PPG-116/66 Copolymer, Hydrogen Peroxide (5% w/v), Silica, Flavor, Sodium Lauryl Sulfate, Tetrasodium Pyrophosphate, Sodium Saccharin, Disodium Pyrophosphate, Sucralose, BHT.

**Questions?**

**1-800-468-6502**

[www.colgateopticwhite.com](http://www.colgateopticwhite.com)

*Dist. by:*

**COLGATE-PALMOLIVE COMPANY**

*New York, NY 10022 U.S.A.*

**PRINCIPAL DISPLAY PANEL - 59 g Tube Label**

Colgate®

Anticavity Fluoride Toothpaste

OPTIC

WHITE®

PRO SERIES

REMOVES

15 YEARS

OF STAINS\*

5%

HYDROGEN

PEROXIDE

STAIN PREVENTION

NET WT 2.1 OZ (59 g)



## COLGATE OPTIC WHITE PRO SERIES STAIN PREVENTION

sodium monofluorophosphate paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35000-747
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)		FLUORIDE ION	1.1 mg in 1 g	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
POLOXAMER 105 (UNII: XPP85ZHV76)		450.3 mg in 1 g		
CROSPVIDONE (UNII: 2S7830E561)				
CALCIUM PYROPHOSPHATE (UNII: X69NU20D19)				
PEG/PPG-116/66 COPOLYMER (UNII: JP0CK963E0)				
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SODIUM ACID PYROPHOSPHATE (UNII: H5WWD9LZUD)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
<b>Product Characteristics</b>				
Color	WHITE	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-747-30	1 in 1 CARTON	11/25/2021	
1		85 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-747-32	1 in 1 CARTON	11/25/2021	
2		93 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:35000-747-21	1 in 1 CARTON	11/25/2021	
3		59 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:35000-747-16	1 in 1 CARTON	11/25/2021	
4		6 g in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing	Application Number or Monograph	Marketing Start	Marketing End	

Category	Citation	Date	Date
OTC MONOGRAPH FINAL	part355	11/23/2021	

**Labeler** - Colgate-Palmolive Company (001344381)

### Establishment

Name	Address	ID/FEI	Business Operations
Mission Hills, S.A. de C.V.		812312122	ANALYSIS(35000-747) , MANUFACTURE(35000-747) , PACK(35000-747) , LABEL(35000-747)

Revised: 10/2019

Colgate-Palmolive Company