# COLGATE OPTIC WHITE ADVANCED SPARKLING WHITE- 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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## $\textbf{Colgate}^{\texttt{@}} \ \textbf{Optic} \ \textbf{White}_{\texttt{@}} \ \textbf{Advanced} \ \textbf{Sparkling} \ \textbf{White}^{\texttt{@}} \ \textbf{Toothpaste}$

**Drug Facts** 

#### Active ingredient

Sodium Monofluorophosphate 0.76% (0.12% 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	brush teeth thoroughly, preferably
children 2	after each meal or at least twice a
years of age	day, or as directed by a dentist or
and older	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**

Propylene Glycol, Calcium Pyrophosphate, PVP, PEG/PPG-116/66 Copolymer, PEG-12, Glycerin, Flavor, Hydrogen Peroxide, Sodium Lauryl Sulfate, Silica, Tetrasodium Pyrophosphate, Sodium Saccharin, Disodium Pyrophosphate, Sucralose, Phosphoric Acid, BHT, Water.

#### Questions?

1-800-468-6502

PRINCIPAL DISPLAY PANEL - 127 g Tube Carton

Colgate® Anticavity Fluoride Toothpaste

NOW 2X WHITENING INGREDIENT<sup>†</sup>

 $\begin{array}{c} OPTIC \\ WHITE_{\Re} \end{array}$ 

ADVANCED

ENAMEL SAFE NET WT 4.5 OZ (127 g)

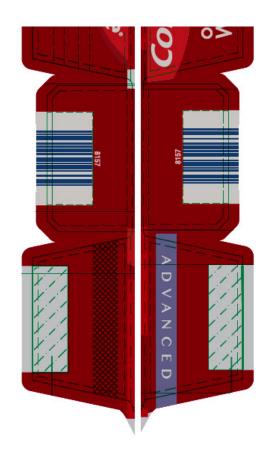
SPARKLING WHITE®

DEEPLY WHITENS FOR UP TO FOUR SHADES\*

HYDROGEN 2% PEROXIDE







### COLGATE OPTIC WHITE ADVANCED SPARKLING WHITE

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-978
Route of Administration	DENTAL		

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

Inactive Ingredients				
Ingredient Name	Strength			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	401.3 mg in 1 g			
CALCIUM PYROPHOSPHATE (UNII: X69 NU20 D19)				
PO VIDO NE K15 (UNII: E54VE15114)				
PEG/PPG-116/66 COPOLYMER (UNII: JP0CK963E0)				
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)				
GLYCERIN (UNII: PDC6A3C0OX)				
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				

SO DIUM PYRO PHO SPHATE (UNII: O352864B8Z)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SO DIUM ACID PYRO PHO SPHATE (UNII: H5WVD9 LZUD)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PHO SPHO RIC ACID (UNII: E4GA8884NN)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
WATER (UNII: 059QF0KO0R)	

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

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:35000-978-86	1 in 1 CARTON	10/14/2019	
1		127 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-978-32	1 in 1 CARTON	10/14/2019	
2		90 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:35000-978-14	1 in 1 CARTON	10/14/2019	
3		41 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:35000-978-16	1 in 1 CARTON	10/14/2019	
4		21.2 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:35000-978-44	2 in 1 CARTON	10/14/2019	
5		127 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:35000-978-76	2 in 1 CARTON	10/14/2019	
6		90 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:35000-978-71	1 in 1 CARTON	11/26/2019	
7		119 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	10/14/2019		

## Labeler - Colgate-Palmolive Company (001344381)