# COLGATE OPTIC WHITE RENEWAL HIGH IMPACT 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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## Colgate® Optic White® Renewal High Impact White 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**

	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**

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<sup>®</sup>

Anticavity Fluoride Toothpaste

NEW

**OPTIC** 

 $WHITE_{\mathbb{R}}$ 

**RENEWAL** 

**REMOVES** 

10 YEARS OF

YELLOW STAINS\*

**HYDROGEN** 

3%

**PEROXIDE** 

HIGH IMPACT WHITE

NET WT 3.0 OZ (85 g)

**ENAMEL SAFE** 





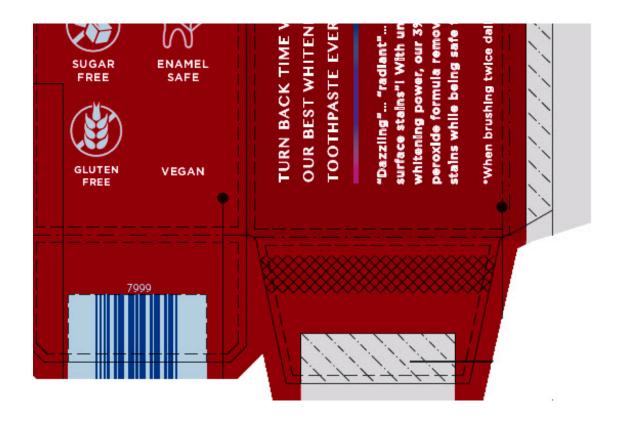


**OUR PATENTED** WHITENING TOOTHPASTE **CONTAINS OUR** HIGHEST LEVEL OF HYDROGEN PEROXIDE, PROVEN TO DEEPLY WHITEN BEYOND SURFACE STAINS.









## **COLGATE OPTIC WHITE RENEWAL HIGH IMPACT WHITE**

sodium monofluorophosphate paste, dentifrice

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-982	
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)	527 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:35000-982- 63	1 in 1 CARTON	11/04/2019		
1		85 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:35000-982- 62	2 in 1 CARTON	11/04/2019		
2		85 g in 1 TUBE; Type 0: Not a Combination Product			
3	NDC:35000-982- 15	1 in 1 CARTON	12/13/2019		
3		20 g in 1 TUBE; Type 0: Not a Combination Product			
4	NDC:35000-982- 41	1 in 1 CARTON	03/13/2020		
4		116 g in 1 TUBE; Type 0: Not a Combination Product			
5	NDC:35000-982- 43	1 in 1 CARTON	04/04/2022		
5		121 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)

Revised: 10/2019 Colgate-Palmolive Company