COLGATE OPTIC WHITE ADVANCED VIBRANT CLEAN- 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.

$Colgate^{\circledR}\ Optic\ White_{\circledR}\ Advanced\ Vibrant\ Clean\ Toothpas\, te$

Drug Facts

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

	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 moore	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, PEG-12, Glycerin, Flavor, Hydrogen Peroxide, Sodium Lauryl Sulfate, Silica, Tetrasodium Pyrophosphate, Sodium Saccharin, Disodium Pyrophosphate, Sucralose, BHT.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 127 g Tube Carton

Colgate[®]

Anticavity Fluoride Toothpaste

NOW 2X WHITENING INGREDIENT †

OPTIC

 $WHITE_{ ext{ ext{ ext{$\mathbb{R}}}}}$

ADVANCED

DEEPLY WHITENS FOR

UP TO FOUR SHADES*

HYDROGEN

2%

PEROXIDE

ENAMEL SAFE

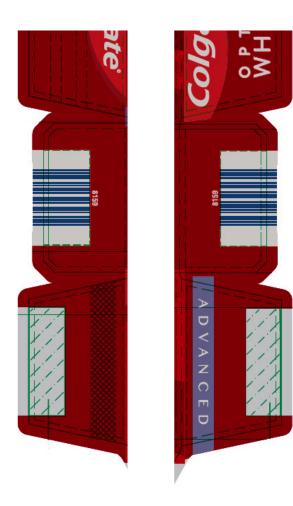
NET WT 4.5 OZ (127 g)

VIBRANT CLEAN









COLGATE OPTIC WHITE ADVANCED VIBRANT CLEAN

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-979
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	1.5 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)	398 mg in 1 g	
CALCIUM PYRO PHO SPHATE (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)		

HYDROGEN PERO XIDE (UNII: BBX060AN9V)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
SODIUM PYROPHO SPHATE (UNII: O352864B8Z)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
SO DIUM ACID PYRO PHO SPHATE (UNII: H5WVD9 LZUD)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	

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:35000-979-32	1 in 1 CARTON	10/14/2019	
1	127 g in 1 TUBE; Type 0: Not a Combination Product		
2 NDC:35000-979-86	1 in 1 CARTON	10/14/2019	
2	90 g in 1 TUBE; Type 0: Not a Combination Product		
3 NDC:35000-979-76	2 in 1 CARTON	10/14/2019	
3	90 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)

Revised: 10/2019 Colgate-Palmolive Company