

COLGATE OPTIC WHITE PROSERIES VIVIDLY FRESH- 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® ProSeries Vividly Fresh

Active ingredient

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

Dist. by:

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

PRINCIPAL DISPLAY PANEL - 85 g Tube Carton

Colgate®
Anticavity Fluoride Toothpaste

OPTIC
WHITE®

PRO SERIES

REMOVES
15 YEARS
OF STAINS*

5%
HYDROGEN
PEROXIDE

VIVIDLY FRESH

NET WT 3.0 OZ (85 g)



COLGATE OPTIC WHITE PROSERIES VIVIDLY FRESH

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-749
Route of Administration	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

Inactive Ingredients

Ingredient Name	Strength
POLOXAMER 105 (UNII: XPP85ZH76)	450 mg in 1 g
CROSPVIDONE (UNII: 2S7830E561)	
CALCIUM PYROPHOSPHATE (UNII: X69NU20D19)	
PEG/PPG-116/66 COPOLYMER (UNII: JPOCK963E0)	
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)	

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:35000-749-30	1 in 1 CARTON	11/25/2021	
1		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	11/23/2021	

Labeler - Colgate-Palmolive Company (001344381)

Establishment

Name	Address	ID/FEI	Business Operations
Mission Hills, S.A. de C.V.		812312122	ANALYSIS(35000-749) , MANUFACTURE(35000-749) , PACK(35000-749) , LABEL(35000-749)

Revised: 10/2019

Colgate-Palmolive Company