

COLGATE OPTIC WHITE ADVANCED ICY 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® Advanced Icy Fresh 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 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

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

PRINCIPAL DISPLAY PANEL - 127 g Tube Carton

Colgate®
Anticavity
Fluoride Toothpaste

NOW
2X WHITENING INGREDIENT†

OPTIC
WHITE®

ADVANCED

ENAMEL SAFE
NET WT 4.5 OZ (127 g)

DEEPLY WHITENS FOR
UP TO FOUR SHADES*

HYDROGEN
2%
PEROXIDE

ICY FRESH

Colgate[®]
Anticavity Fluoride Toothpaste

ENAMEL SAFE NET WT 4.5 OZ (127 g)

ICY FRESH

OPTIC
WHITE.
ADVANCED

DEEPLY WHITENS FOR
UP TO FOUR SHADES*



NOW 2X WHITENING INGREDIENT†

Colgate[®]
Anticavity Fluoride Toothpaste

ENAMEL SAFE NET WT 4.5 OZ (127 g)

ICY FRESH

OPTIC
WHITE.
ADVANCED

DEEPLY WHITENS FOR
UP TO FOUR SHADES*



NOW 2X WHITENING INGREDIENT†

Drug Facts

Active ingredient Purpose
Sodium Monofluorophosphate
0.76% (0.12% w/v fluoride ion).....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.

Drug Facts (continued)

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 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

Some people may experience tooth sensitivity or gum discomfort when using whitening products. This discomfort is temporary and not harmful. If you experience more than mild tooth sensitivity, stop use and consult your dentist.



GLUTEN FREE



Colgate[®]

OPTIC
WHITE.
ADVANCED



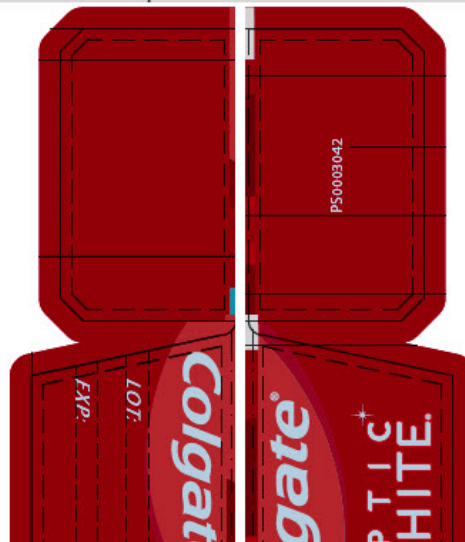
GOES BEYOND SURFACE STAINS
WITH OUR PATENTED 2%
HYDROGEN PEROXIDE FORMULA

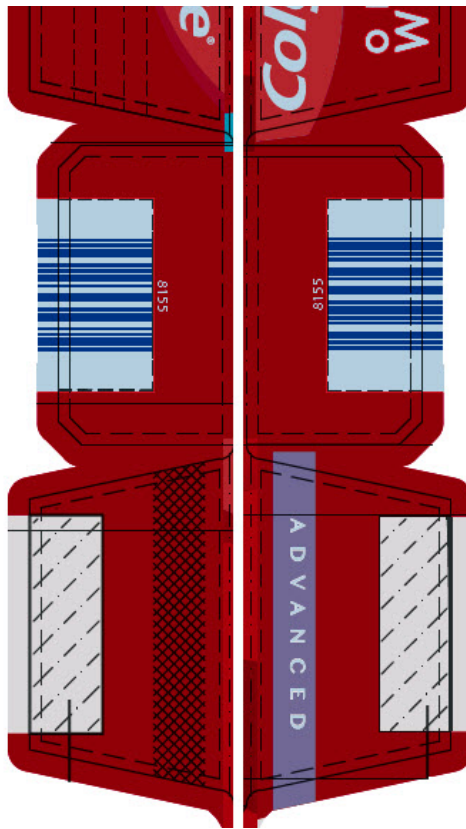
DEEPLY WHITENS
FOR UP TO
FOUR SHADES*

ENAMEL
SAFE



* when brushing twice daily for six weeks
† twice the level of hydrogen peroxide vs. previous Colgate[®] Optic White[®] Advanced





COLGATE OPTIC WHITE ADVANCED ICY FRESH

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-977
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)	401.8 mg in 1 g
CALCIUM PYROPHOSPHATE (UNII: X69NU20D19)	
POVIDONE K15 (UNII: E54VE15114)	
PEG/PPG-116/66 COPOLYMER (UNII: JP0CK963E0)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM ACID PYROPHOSPHATE (UNII: H5WVD9LZUD)	
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:35000-977-86	1 in 1 CARTON	10/14/2019	
1		127 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-977-32	1 in 1 CARTON	10/14/2019	
2		90 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:35000-977-44	2 in 1 CARTON	10/14/2019	
3		127 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:35000-977-76	2 in 1 CARTON	10/14/2019	
4		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