COLGATE OPTIC WHITE STAIN FIGHTER FRESH MINT- sodium fluoride 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 ${}_{\circledR}$ Stain Fighter ${}^{\circledR}$ Fresh Mint

Drug Facts

Active ingredient

Sodium Fluoride 0.24% (0.15% 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

2 years of age and	brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician
Vears	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

Water, Sorbitol, Hydrated Silica, PEG-12, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Potassium Hydroxide, Tetrasodium Pyrophosphate, Phosphoric Acid, Cocamidopropyl Betaine, Sodium Saccharin, Benzyl Alcohol, Mica, Blue 1, Titanium Dioxide.

Questions?

1-800-468-6502

Dist. by:

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

PRINCIPAL DISPLAY PANEL - 56.6 g Tube Carton

Colgate $^{\$}$ Anticavity Fluoride Toothpaste OPTIC WHITE $^{\$}$ STAIN FIGHTER $^{\$}$

REMOVES 5X MORE SURFACE STAINS* WITH MICRO-POLISHING ACTION

FRESH MINT GEL ENAMEL SAFE NET WT 2.0 OZ (56.6 g)

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sodium fluoride paste, dentifrice

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:35000-263

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CORUM EL MORIDE (MINIL OTYGOLATAME) (FL MORIDE ION LININ COOMENACO)	FILLIONINE IONI	

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION 1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KOOR)	191.18 mg in 1 g
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
MICA (UNII: V8A1AW0880)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Color	BLUE	Score
Shape		Size
Flavor	MINT	Imprint Code
Contains		

Packaging									
#	Item Code	Package Description	Marketing Start Date	Marketing End Date					
1	NDC:35000-263-71	1 in 1 CARTON	06/01/2022						
1		119 g in 1 TUBE; Type 0: Not a Combination Product							
2	NDC:35000-263-02	1 in 1 CARTON	06/01/2022						
2		56.6 g in 1 TUBE; Type 0: Not a Combination Product							
3	NDC:35000-263-60	1 in 1 CARTON	06/01/2022						
3		170 g in 1 TUBE; Type 0: Not a Combination Product							
4	NDC:35000-263-33	1 in 1 CARTON	06/01/2022						
4		36.8 g in 1 TUBE; Type 0: Not a Combination Product							
5	NDC:35000-263-30	1 in 1 CARTON	06/01/2022						
5		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	06/01/2022							

Labeler - Colgate-Palmolive Company (001344381)

Revised: 6/2022 Colgate-Palmolive Company