COLGATE OPTIC WHITE CHARCOAL- 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® OPTIC WHITE® CHARCOAL

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

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

Water, Sorbitol, Hydrated Silica, PEG-12, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Potassium Hydroxide, Tetrasodium Pyrophosphate, Phosphoric Acid, Cocamidopropyl Betaine, Sodium Saccharin, Benzyl Alcohol, Charcoal Powder, Blue 1, Red 40, Titanium Dioxide.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 119 g Tube Carton

Colgate® Anticavity Fluoride Toothpaste

OPTIC
WHITE®
WITH CHARCOAL

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

COOL MINT PASTE

ENAMEL SAFE

NET WT 4.2 OZ (119 g)



COLGATE OPTIC WHITE CHARCOAL

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-262
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1 mg in 1 g	

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	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)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:35000-262- 71	1 in 1 CARTON	06/01/2022	
1		119 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-262- 02	1 in 1 CARTON	06/01/2022	
2		56.6 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:35000-262- 60	1 in 1 CARTON	06/01/2022	
3		170 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:35000-262- 33	1 in 1 CARTON	06/01/2022	
4		36.8 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:35000-262- 30	1 in 1 CARTON	06/01/2022	
5		85 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC MONOGRAPH FINAL	part355	06/01/2022	

Labeler - Colgate-Palmolive Company (001344381)

Revised: 6/2022 Colgate-Palmolive Company