COLGATE MAX FRESH ADVANCED WHITENING- sodium fluoride gel, 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® Max Fresh® Advanced Whitening

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

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 the child's brushing and rinsing (to minimize swallowing)
children under 2 years	ask a dentist or physician

Inactive ingredients

Sorbitol, Water, Hydrated Silica, PEG-12, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Tetrasodium Pyrophosphate, Cocamidopropyl Betaine, Sodium Saccharin,

Hydroxypropyl Methylcellulose, Blue 1, Titanium Dioxide, Yellow 5.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 170 g Tube Carton

Colgate® Anticavity Fluoride Toothpaste

10X LONGER LASTING COOL[†]

Max Fresh_® ADVANCED WHITENING

EXTRA WHITENING POWER‡

NET WT 6.0 OZ (170 g)

CLEAN MINT



COLGATE MAX FRESH ADVANCED WHITENING

sodium fluoride gel, dentifrice

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:35000-899

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | SODIUM FLUORIDE | 2.4 mg in 1 g

Inactive Ingredients

mactive myredients			
Ingredient Name	Strength		
SORBITOL (UNII: 506T60A25R)	564.38 mg in 1 g		
WATER (UNII: 059QF0KO0R)			
HYDRATED SILICA (LINII: Y607T4G8P9)			

POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)	

Product Characteristics			
Color	BLUE (LIGHT BLUE WITH WHITE FILM)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-899- 60	1 in 1 CARTON	10/16/2021	
1		170 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-899- 95	1 in 1 CARTON	10/16/2021	
2		178 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:35000-899- 34	2 in 1 CARTON	10/16/2021	
3		170 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	10/16/2021		

Labeler - Colgate-Palmolive Company (001344381)