

COLGATE RENEWAL WHITENING RESTORATION- stannous 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® Renewal Whitening Restoration

Drug Facts

Active ingredient

Stannous Fluoride 0.454% (0.15% w/v fluoride ion)

Purposes

Anticavity, Antigingivitis, Antisensitivity

Uses

- aids in the prevention of cavities
- helps prevent gingivitis
- helps interfere with harmful effects of plaque associated with gingivitis
- builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact

Warnings

When using this product for sensitivity, do not use longer than 4 weeks unless recommended by a dentist.

Stop use and ask a dentist if the sensitivity problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.

Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a dentist if

- gingivitis, bleeding, or redness persists for more than 2 weeks
- you have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the teeth. These may be signs of periodontitis, a serious form of gum disease.

Directions

- **adults and children 12 years of age and older:** apply at least a 1-inch strip of the product onto a soft bristled toothbrush. Brush teeth thoroughly for at least 1

minute twice a day (morning and evening) or as recommended by a dentist. Make sure to brush all sensitive areas of the teeth.

- do not swallow.
- **children under 12 years of age:** consult a dentist.

Other information

- products containing stannous fluoride may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.
- this Colgate product is specially formulated to help prevent staining.

Inactive ingredients

Sorbitol, Water, Hydrated Silica, PEG-12, Flavor, Sodium Lauryl Sulfate, Tetrasodium Pyrophosphate, Potassium Nitrate, Xanthan Gum, Sodium Saccharin, Cocamidopropyl Betaine, Sodium Hyaluronate, Blue 1, Yellow 10.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE CO.

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 85 g Tube Carton

Colgate®

Anticavity, Antigingivitis and Antisensitivity Toothpaste

GUM

RENEWAL

REVITALIZES

GUMS

BY REVERSING

EARLY DAMAGE

CLEANSING

3X

ACTION*

WHITENING

NET WT 3.0 OZ (85 g)

GEL



COLGATE RENEWAL WHITENING RESTORATION

stannous fluoride gel, dentifrice

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:35000-220

Route of Administration		DENTAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	1.1 mg in 1 g	
Inactive Ingredients				
Ingredient Name		Strength		
SORBITOL (UNII: 506T60A25R)				
WATER (UNII: 059QF0KO0R)				
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)				
POTASSIUM NITRATE (UNII: RU45X2JN0Z)				
XANTHAN GUM (UNII: TTV12P4NEE)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)				
HYALURONATE SODIUM (UNII: YSE9PPT4TH)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
Product Characteristics				
Color	TURQUOISE	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-220-32	1 in 1 CARTON	11/03/2020	12/31/2024
1		90 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-220-63	1 in 1 CARTON	11/03/2020	12/31/2024
2		85 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:35000-220-20	1 in 1 CARTON	02/03/2021	12/31/2024
3		23.8 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	11/03/2020	12/31/2024

Labeler - Colgate-Palmolive Company (001344381)

Establishment

Name	Address	ID/FEI	Business Operations
Colgate-Palmolive Company		785047999	ANALYSIS(35000-220) , LABEL(35000-220) , MANUFACTURE(35000-220) , PACK(35000-220)

Revised: 11/2020

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