COLGATE GUM RENEWAL DEEP CLEAN- 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® Gum Renewal Deep Clean

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, Blue 1.

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*

DEEP CLEAN

NET WT 3.0 OZ (85 g)

GEL



COLGATE GUM RENEWAL DEEP CLEAN

stannous fluoride gel, dentifrice

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:35000-219

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: 50CF3011KX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

F	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:35000-219- 63	1 in 1 CARTON	03/04/2022	12/31/2024		
1		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	03/04/2022	12/31/2024	

Labeler - Colgate-Palmolive Company (001344381)

Revised: 6/2022