#### COLGATE RENEWAL SENSITIVITY REPAIR- 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.

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## Colgate<sup>®</sup> Renewal Sensitivity Repair

#### 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, Sodium Lauryl Sulfate, Tetrasodium Pyrophosphate, Flavor, Potassium Nitrate, Xanthan Gum, Sodium Saccharin, Cocamidopropyl Betaine, 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

 $\mbox{Colgate}^{\mbox{$\mathbb{8}$}}$  Anticavity, Antigingivitis and Antisensitivity Toothpaste

GUM

RENEWAL

REVITALIZES GUMS BY REVERSING EARLY DAMAGE

CLEANSING 3X ACTION\*

SENSITIVITY

NET WT 3.0 OZ (85 g) GEL



## **COLGATE RENEWAL SENSITIVITY REPAIR**

stannous fluoride gel, dentifrice

# Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:35000-224

STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE I Inactive Ingredients Ingredient Name SORBITOL (UNII: 506T60A25R) WATER (UNII: 0590F0KOOR) HYDRATED SILICA (UNII: Y607T4G8P9) POLYETHYLENE GLYCOL 600 (UNII: NL4j9F21N9) SODIUM LAURYL SULFATE (UNII: 368GB5141)) SODIUM LAURYL SULFATE (UNII: 368GB5141)) SODIUM PYROPHOSPHATE (UNII: 035286488Z) POTASSIUM NITRATE (UNII: R045X2JN0Z) XANTHAN GUM (UNII: TM22P4NEE) SACCHARIN SODIUM (UNII: SDEZUX40TY) COCAMIDOPROPYL BETAINE (UNII: S0CF3011KX) FD&C BLUE NO. 1 (UNII: BR47X3TBD) D&C YELLOW NO. 10 (UNII: 355W5USQ3G)  Product Characteristics Color GREEN Size Flavor MINT Imprint Code Contains III A R00 MINT Imprint Code  Packaging # Item Code Package Description 11/03/2020  A b g in 1 TUBE; Type 0: Not a Combination Marketing Information						
Ingredient Name       Basis of         STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O) FLUORIDE I         Inactive Ingredients         Ingredient Name         SORBITOL (UNII: 506T60A25R)         WATER (UNII: 059QF0KOOR)         HYDRATED SILICA (UNII: Y607T4G8P9)         POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)         SODIUM LAURYL SULFATE (UNII: 0352864B82)         POTASSIUM NITRATE (UNII: R045X2JN02)         XANTHAN GUM (UNII: TTV12P4NEE)         SACCHARIN SODIUM (UNII: B88ZUX40TY)         COCCAMIDOPROPYL BETAINE (UNII: S051011XX)         FD6X BLUE NO. 10 (UNII: H3R47K3TBD)         D6K YELLOW NO. 10 (UNII: 35SW5USQ3G)         MINT         Packaging         #       Item Code       Package Description       Marketing Start Date         1       NDC:35000-224-       1 in 1 CARTON       11/03/2020         1       B3 g in 1 TUBE; Type 0: Not a Combination       11/03/2020						
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SORBITOL (UNII: S06760A25R)         WATER (UNII: 059QF0K00R)         HYDRATED SILICA (UNII: Y607T4G8P9)         POLYSTER (UNII: S05740G8P9)         SODIUM LAURYL SULFATE (UNII: NL4J9F21N9)         SODIUM LAURYL SULFATE (UNII: 368GB5141))         SODIUM PYROPHOSPHATE (UNII: 3035286488Z)         POTASSIUM NITRATE (UNII: S035286488Z)         SODIUM (UNII: TTV12PANEE)         SACCHARIN SODIUM (UNII: TTV12PANEE)         SACCHARIN SODIUM (UNII: S08ZUX40TY)         COCAMIDOPROPYL BETAINE (UNII: S0CF3011KX)         FD& UNII: 355V5USQ3G)         Socretion (UNII: 355V5USQ3G)    Product Characteristics          Socre         Socretion         Socretion         Socretion         Socretion         Socretion         Socretion						
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SACCHARIN SODIUM (UNII: SB8Z UX40TY)         COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)         FD&C BLUE NO. 1 (UNII: H3R47K3TBD)         D&C YELLOW NO. 10 (UNII: 355W5USQ3G)         Product Characteristics         Color       GREEN         Score         Shape       GREEN         Flavor       MINT         MINT         Ode Score         Protectaging         #       Item Code         Package Description       Marketing Start Date         1       NDC:35000-224-       1 in 1 CARTON       11/03/2020         1       NDC:35000-224-       1 in 1 CARTON       11/03/2020         1       Sig in 1 TUBE; Type 0: Not a Combination       11/03/2020	POTASSIUM NITRATE (UNII: RU45X2JNOZ)					
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Fb&C BLUE NO. 1 (UNII: H3R47K3TBD)         D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)         GREEN         Score         GREEN         Size         Imprint Code         Size         Flavor         MINT         Marketing Start Date         Package Description         Marketing Start Date         1 in 1 CARTON         1 NDC: 35000-224- 63       1 in 1 CARTON       11/03/2020         I in 1 CARTON         Product						
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Color       GREEN       Score         Shape       Imprint Code       Size         Flavor       MINT       Imprint Code         Color tains       Package Description       Marketing Start Date         1       NDC: 35000-224- 63       1 in 1 CARTON       11/03/2020         1       NDC: 35000-224- 63       1 in 1 CARTON       11/03/2020         1       S5 g in 1 TUBE; Type 0: Not a Combination Product       11/03/2020	D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)					
Color       GREEN       Score         Shape       Imprint Code       Size         Flavor       MINT       Imprint Code         Color tains       Package Description       Marketing Start Date         1       NDC: 35000-224- 63       1 in 1 CARTON       11/03/2020         1       NDC: 35000-224- 63       1 in 1 CARTON       11/03/2020         1       S5 g in 1 TUBE; Type 0: Not a Combination Product       11/03/2020						
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Item Code       Package Description       Marketing Start Date         1       NDC:35000-224- 63       1 in 1 CARTON       11/03/2020         1       S5 g in 1 TUBE; Type 0: Not a Combination Product       11/03/2020	Size					
Item Code       Package Description       Marketing Start Date         1       NDC:35000-224- 63       1 in 1 CARTON       11/03/2020         1       S5 g in 1 TUBE; Type 0: Not a Combination Product       Start Date	Imprint Code					
#       Item Code       Package Description       Marketing Start Date         1       NDC:35000-224- 63       1 in 1 CARTON       11/03/2020         1       S5 g in 1 TUBE; Type 0: Not a Combination Product       1000000000000000000000000000000000000						
#       Item Code       Package Description       Marketing Start Date         1       NDC:35000-224- 63       1 in 1 CARTON       11/03/2020         1       S5 g in 1 TUBE; Type 0: Not a Combination Product       1000000000000000000000000000000000000						
#     Item Code     Package Description     Date       1     NDC:35000-224- 63     1 in 1 CARTON     11/03/2020       1     85 g in 1 TUBE; Type 0: Not a Combination Product     Not a Combination						
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Labeler - Colgate-Palmolive Company (001344381)

Establishment					
Name	Address	ID/FEI	Business Operations		
Colgate-Palmolive Company		785047999	ANALYSIS(35000-224), LABEL(35000-224), MANUFACTURE(35000-224), PACK(35000-224)		

Revised: 11/2020

Colgate-Palmolive Company