

**COLGATE TOTAL SF MINT STRIPE GEL- stannous 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® Total™<sup>SF</sup> Mint Stripe Gel**

***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**

water, sorbitol, hydrated silica, glycerin, PEG-12, tetrasodium pyrophosphate, sodium lauryl sulfate, microcrystalline cellulose, sodium citrate, zinc phosphate, flavor, cellulose gum, sodium saccharin, cocamidopropyl betaine, xanthan gum, citric acid, sucralose, mica, titanium dioxide, blue 1, yellow 10

### **Questions?**

**1-800-468-6502**

*Dist by:*

**COLGATE-PALMOLIVE CO.**

*New York, NY 10022 U.S.A.*

### **PRINCIPAL DISPLAY PANEL - 2 Tube Carton**

Colgate®

Anticavity, Antigingivitis and Antisensitivity Toothpaste

☐CAVITIES ☐PLAQUE ☐GINGIVITIS ☐ENAMEL ☐TARTAR ☐BREATH ☐WHITENS  
now with SENSITIVITY RELIEF

PROTECTS TEETH, TONGUE, CHEEKS & GUMS  
SEE NEW INFORMATION AND DIRECTIONS

TWO 4.8 OZ (136 g) TUBES  
TOTAL NET WT 9.6 OZ (272 g)

VALUE 2 PACK

NEW ACTIVE INGREDIENT  
STANNOUS FLUORIDE

Total™<sup>SF</sup>

WHOLE MOUTH HEALTH

FRESH  
MINT STRIPE

Gel

# Colgate®

Anticavity, Antigingivitis and Antisensitivity Toothpaste

✓ CAVITIES ✓ PLAQUE ✓ GINGIVITIS ✓ ENAMEL ✓ TARTAR ✓ BREATH ✓ WHITENS  
now with **SENSITIVITY RELIEF**

PROTECTS TEETH, TONGUE, CHEEKS & GUMS

TWO 4.8 OZ (136 g) TUBES • TOTAL NET WT 9.6 OZ (272 g)



VALUE 2 PACK

NEW ACTIVE INGREDIENT  
STANNOUS FLUORIDE

FRESH  
MINT STRIPE



# Colgate®

Anticavity, Antigingivitis and Antisensitivity Toothpaste

✓ CAVITIES ✓ PLAQUE ✓ GINGIVITIS ✓ ENAMEL ✓ TARTAR ✓ BREATH ✓ WHITENS  
now with **SENSITIVITY RELIEF**

PROTECTS TEETH, TONGUE, CHEEKS & GUMS

VALUE 2 PACK

# Colgate®

Anticavity, Antigingivitis and Antisensitivity Toothpaste

✓ CAVITIES ✓ PLAQUE ✓ GINGIVITIS ✓ ENAMEL ✓ TARTAR ✓ BREATH ✓ WHITENS  
now with **SENSITIVITY RELIEF**

PROTECTS TEETH, TONGUE, CHEEKS & GUMS

TWO 4.8 OZ (136 g) TUBES  
TOTAL NET WT 9.6 OZ (272 g)

SEE NEW INFORMATION AND DIRECTIONS



NEW ACTIVE INGREDIENT  
STANNOUS FLUORIDE

FRESH  
MINT STRIPE



Colgate® Total SF  
WHOLE MOUTH HEALTH

WHOLE MOUTH HEALTH®

PROTECTS

✓ TEETH ✓ TONGUE ✓ CHEEKS ✓ GUMS

\*Helps reduce plaque that leads to gingivitis; fortifies enamel; helps relieve sensitivity with continued use. Not intended for prevention or treatment of more serious oral conditions.

FRESH  
MINT STRIPE

Long lasting fresh breath



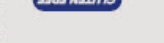
app enabled  
scan for more information



Colgate-Palmolive Co.  
New York, NY 10022 U.S.A.  
www.colgate.com

GLUTEN FREE

www.colgate.com/savewater



SAVE WATER

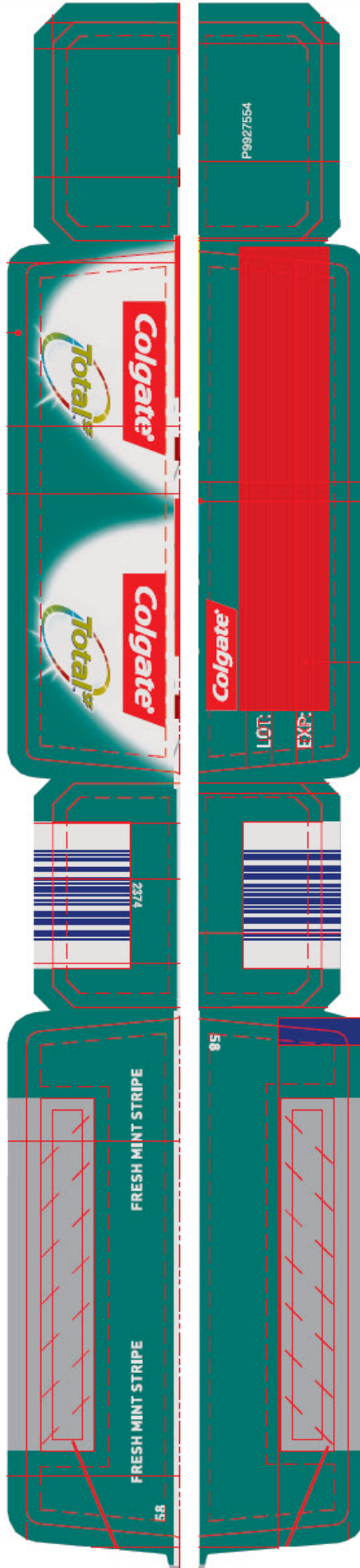
**Drug Facts**  
Active ingredient: Stannous fluoride (0.15% w/w fluoride ion), Amoxicillin, Antisensitivity.  
Purposes: Helps prevent gingivitis; helps interfere with harmful effects of plaque associated with gingivitis; acts in the prevention of cavities.  
Uses: Acts in the prevention of cavities; helps prevent gingivitis; helps interfere with harmful effects of plaque associated with gingivitis.  
Warnings: When using this product for sensitivity, do not use longer than 4 weeks unless recommended by a dentist.  
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: Water, sorbitol, hydrated silica, glycerin, PEG-12, tetrasodium pyrophosphate, sodium lauryl sulfate, microcrystalline cellulose, sodium citrate, zinc phosphate, flavor, xanthan gum, sodium saccharin, coconutdipropyl betaine, xanthan gum, tric acid, sorbitol, ment, titanium dioxide, blue 1, yellow 10.  
Questions? 1-800-468-6502

**Drug Facts**  
Active ingredient: Stannous fluoride (0.15% w/w fluoride ion), Amoxicillin, Antisensitivity.  
Purposes: Helps prevent gingivitis; helps interfere with harmful effects of plaque associated with gingivitis; acts in the prevention of cavities.  
Uses: Acts in the prevention of cavities; helps prevent gingivitis; helps interfere with harmful effects of plaque associated with gingivitis.  
Warnings: When using this product for sensitivity, do not use longer than 4 weeks unless recommended by a dentist.  
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: Water, sorbitol, hydrated silica, glycerin, PEG-12, tetrasodium pyrophosphate, sodium lauryl sulfate, microcrystalline cellulose, sodium citrate, zinc phosphate, flavor, xanthan gum, sodium saccharin, coconutdipropyl betaine, xanthan gum, tric acid, sorbitol, ment, titanium dioxide, blue 1, yellow 10.  
Questions? 1-800-468-6502

NEW INFORMATION & DIRECTIONS

\*This glue flap can be extended to accommodate supplier requirements. It must

This graphic can be extended to accommodate supplier requirements. It must comply with the CP Quality gluing standards."



# COLGATE TOTAL SF MINT STRIPE GEL

stannous fluoride paste, dentifrice

## Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:35000-174 |
| 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 |
|--|----------|
| WATER (UNII: 059QF0KO0R)   |          |
| SORBITOL (UNII: 506T60A25R)  |          |
| HYDRATED SILICA (UNII: Y6O7T4G8P9)                                 |          |
| GLYCERIN (UNII: PDC6A3C0OX)  |          |
| POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)                         |          |
| SODIUM PYROPHOSPHATE (UNII: O352864B8Z)                            |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)                           |          |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)                      |          |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)                |          |
| ZINC PHOSPHATE (UNII: 1E2MCT2M62)                                  |          |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) |          |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)                                |          |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)                          |          |
| XANTHAN GUM (UNII: TTV12P4NEE)                                     |          |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)                           |          |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                                       |          |
| MICA (UNII: V8A1AW0880)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                                |          |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)                                 |          |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)                               |          |

## Product Characteristics

|          |       |              |  |
|----------|-------|--------------|--|
| Color    | GREEN | Score        |  |
| Shape    |       | Size         |  |
| Flavor   | MINT  | Imprint Code |  |
| Contains |       |              |  |

## Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:35000-174-48 | 1 in 1 CARTON                                      | 11/01/2018           |                    |
| 1 |                  | 136 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:35000-174-96 | 2 in 1 CARTON                                      | 11/01/2018           |                    |
| 2 |                  | 136 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |
| 3 | NDC:35000-174-95 | 1 in 1 CARTON                                      | 11/01/2018           |                    |
| 3 |                  | 178 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |
| 4 | NDC:35000-174-78 | 1 in 1 CARTON                                      | 11/01/2018           |                    |
| 4 |                  | 221 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                                  | 11/01/2018           |                    |

**Labeler** - Colgate-Palmolive Company (001344381)

### Establishment

| Name              | Address | ID/FEI    | Business Operations    |
|-------------------|---------|-----------|------------------------|
| Colgate-Palmolive |         | 785047999 | MANUFACTURE(35000-174) |

Revised: 12/2019

Colgate-Palmolive Company