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.

$Colgate^{\circledR}\ Total_{^{TM}}{}^{SF}\ Mint\ Stripe\ Gel$

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 senitivity 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

 $\mathsf{Total}_{\mathsf{TM}}^{\mathsf{SF}}$ WHOLE MOUTH HEALTH

FRESH MINT STRIPE

Gel

olaate

CAVITIES PLAQUE GINGIVITS PARAMEL TARTAR BREATH WHITENS NOW with SENSITIVITY RELIEF

PROTECTS TEETH, TONGUE, CHEEKS & GUMS

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





Colgate

✓ CAVITIES ✓ PLAQUE ✓ GINGIVITIS ✓ ENAMEL ✓ TARTAR ✓ BREATH ✓ WHITENS

now with SENSITIVITY RELIEF

PROTECTS TEETH, TONGUE, CHEEKS & GUMS

VALUE 2 PACK

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scan for more information

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COLGATE-PALMOLIVE CO

GLUTEN FREE

MATER

SAVE





WHOLE MOUTH HEALTH

PROTECTS

✓ TEETH ✓ TONGUE ✓ CHEEKS ✓ GUMS

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

Drug Facts (continued)

Directions

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Drug Facts (continued)

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

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Drug Facts

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Drug Facts

NEW INFORMATION & DIRECTIONS

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Other information

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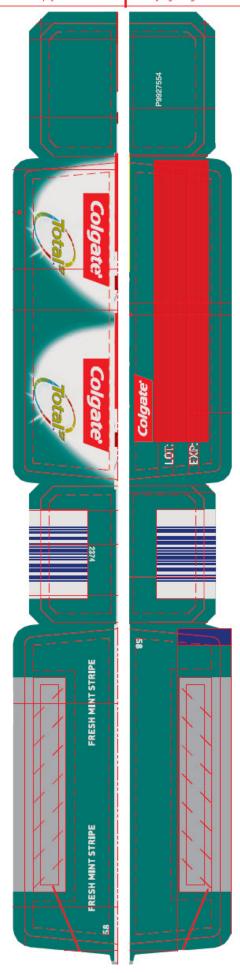
Drug Facts (continued)

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Questions? 1-800-468-6502

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

Drug Facts (continued)



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 PYROPHO SPHATE (UNII: O352864B8Z)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			
SO DIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)			
ZINC PHO SPHATE (UNII: 1E2MCT2M62)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679 OBS 311)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)			
XANTHAN GUM (UNII: TTV12P4NEE)			
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
MICA (UNII: V8 A1AW0 880)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
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	11/0 1/20 18	
1		136 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-174-96	2 in 1 CARTON	11/0 1/20 18	
2		136 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:35000-174-95	1 in 1 CARTON	11/0 1/20 18	
3		178 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:35000-174-78	1 in 1 CARTON	11/0 1/20 18	
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	11/0 1/20 18	

Labeler - Colgate-Palmolive Company (001344381)

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

Revised: 12/2019 Colgate-Palmolive Company