COLGATE TOTAL SF CLEAN MINT- 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_{TM}SF Clean Mint Paste

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, titanium dioxide

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

 $\hbox{\tt @CAVITIES @PLAQUE @GINGIVITIS @ENAMEL @TARTAR @BREATH @WHITENS now with SENSITIVITY RELIEF}$

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

 $Total_{TM}^{SF}$ WHOLE MOUTH HEALTH

NEW ACTIVE INGREDIENT STANNOUS FLUORIDE

CLEAN MINT

Paste

VALUE 2 PAC

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CAVITIES PLAGUE GINGMITS PAREL TARTAR BREATH WHITENS NOW WITH SENSITIVITY RELIEP

PROTECTS TEETH, TONGUE, CHEEKS & GUMS

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• now with SENSITIVITY RELIEF

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NEW ACTIVE INGREDIENT STANNOUS FLUORIDE



WHOLE MOUTH HEALTH

PROTECTS

✓ TEETH ✓ TONGUE ✓ CHEEKS ✓ GUMS

"Helps reduce plaque that leads to gingivitis; fortifies enamel; helps relieve sensitivity with

CLEAN MINT

Helps prevent plaque buildup and fights tartar



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WWW.colgateloak.or.

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Questions? 1-800-468-6502

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Active ingredient

Drug Facts

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Orug Facts (continued)

Questions? 1-800-468-6502

comply with the CP Quality gluing standards." EXP. HOT CLEAN MINT CLEAN MINT

COLGATE TOTAL SF CLEAN MINT

stannous fluoride paste, dentifrice

Product Information

Route of Administration DENTAL

Active Ingredient/Active Moiety

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Iı	Ingredient Name		Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR4	.44B32Q) (FLUORIDE ION - UNII:Q80\	/PU408O)	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)				
SO DIUM LAURYL SULFATE (UNII: 368 GB5141J)				
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
ZINC PHO SPHATE (UNII: 1E2MCT2M62)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679 OBS 311)				
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)				
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)				
XANTHAN GUM (UNII: TTV12P4NEE)				
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				

Product Characteristics

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:35000-172-25	1 in 1 CARTON	11/0 1/20 18		
1		24.9 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:35000-172-14	1 in 1 CARTON	11/01/2018		

2		39 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:35000-172-32	1 in 1 CARTON	11/0 1/20 18	
3		93 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:35000-172-48	1 in 1 CARTON	11/0 1/20 18	
4		136 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:35000-172-96	2 in 1 CARTON	11/0 1/20 18	
5		136 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(35000-172)	

Revised: 12/2019 Colgate-Palmolive Company