COLGATE TOTAL SF ADVANCED WHITENING- 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^{IIM}SF Advanced Whitening 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
- if 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

glycerin, hydrated silica, water, propylene glycol, PEG-12, pentasodium triphosphate, sodium citrate, sodium lauryl sulfate, flavor, PVP, microcrystalline cellulose, trisodium phosphate, zinc oxide, citric acid, zinc citrate, phosphoric acid, sodium saccharin, cocamidopropyl betaine, carrageenan, xanthan gum, PVM/MA copolymer, 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

 $\verb||CAVITIES||PLAQUE||GINGIVITIS||ENAMEL||TARTAR||BREATH||WHITENS||now with SENSITIVITY RELIEF||$

PROTECTS TEETH, TONGUE, CHEEKS & GUMS

SEE NEW INFORMATION AND DIRECTIONS

TWO 5.1 OZ (144 g) TUBES TOTAL NET WT 10.2 OZ (288 g)

VALUE 2 PACK

NEW ACTIVE INGREDIENT STANNOUS FLUORIDE

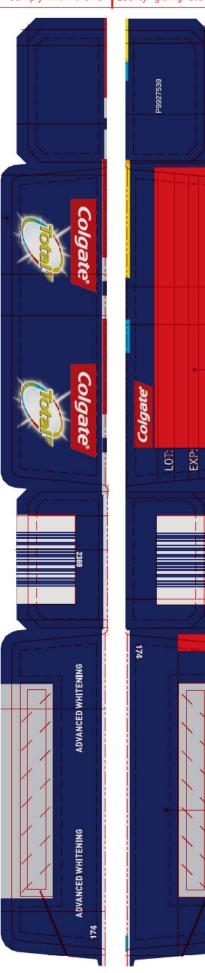
Total^{™SF} WHOLE MOUTH HEALTH

ADVANCED WHITENING

Paste



This alue flap can be extended to accommodate supplier requerimentes. It must



COLGATE TOTAL SF ADVANCED WHITENING

stannous fluoride paste, dentifrice

Product Information									
Product T ype	HUMAN OTC DRUG	Item Code (Source	Item Code (Source) NDC:350		00-171				
Route of Administration	DENTAL	nem coue (source)						
Route of Administration	DENTAL								
Active Ingredient/Active Mo	ietv								
-	ngredient Name		Basis of St	rength	Strength				
	Ingredient Name Dasis of Strengt NNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O) FLUORIDE ION				1.1 mg in 1 g				
FLUCKIDE (UNIL SFIR44B52Q) (FLUCKIDE ION - UNILQ00 VP04000) FLUCKIDE ION									
Inactive Ingredients									
	Ingredient Na	me			Strength				
WATER (UNII: 059QF0KO0R)									
SORBITOL (UNII: 506T60A25R)									
HYDRATED SILICA (UNII: Y6O7T4G8	P9)								
GLYCERIN (UNII: PDC6A3C0OX)									
POLYETHYLENE GLYCOL 600 (UN	II: NL4J9F21N9)								
SODIUM PYROPHOSPHATE (UNII: C									
SODIUM LAURYL SULFATE (UNII: 3									
MICROCRYSTALLINE CELLULOSE									
	SO DIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)								
ZINC PHO SPHATE (UNII: 1E2MCT2M									
CARBOXYMETHYLCELLULOSE SC		$\mathbf{K}\mathbf{M}$ (UNII: K6/90B5311)							
SACCHARIN SODIUM (UNII: SB8ZUX40TY) COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)									
PROPYLENE GLYCOL (UNII: 6DC9C									
XANTHAN GUM (UNII: TTV12P4NEE)									
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)									
SUCRALOSE (UNII: 96K6UQ3ZD4)									
MICA (UNII: V8A1AW0880)									
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)									
FD&C BLUE NO.1 (UNII: H3R47K3TBD)									
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)									
Product Characteristics									
Color	WHITE	Score							
Shape		Size							
Flavor	MINT	Imprint Code							
Contains									
Packaging									

. . .

#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:35000-171-25	1 in 1 CARTON	11/0 1/20 18	0 1/0 1/20 22			
1	24.9 g in 1 TUBE; Type 0: Not a Combination Product						
2	NDC:35000-171-93	1 in 1 CARTON	11/0 1/20 18	0 1/0 1/20 22			
2 96 g in 1 TUBE; Type 0: Not a Combination Product							
3 NDC:35000-171-47 1 in 1 CARTON		1 in 1 CARTON	11/0 1/20 18	0 1/0 1/20 22			
3		144 g in 1 TUBE; Type 0: Not a Combination Product					
4	NDC:35000-171-65	2 in 1 CARTON	11/0 1/20 18	0 1/0 1/20 22			
4		144 g in 1 TUBE; Type 0: Not a Combination Product					
5	NDC:35000-171-64	1 in 1 CARTON	11/0 1/20 18	0 1/0 1/20 22			
5		181 g in 1 TUBE; Type 0: Not a Combination Product					
7	√ −−1−−↓ ¹ −− <i>×</i> − − −↓	4°					
Marketing Information							
Marketing Category		y Application Number or Monograph Citation	n Marketing Start Date	Marketing End Date			
			11/01/2018				

Labeler - Colgate-Palmolive Company (001344381)

Establishment

Name	Address	ID/FEI	Business Operations
Colgate-Palmolive		785047999	MANUFACTURE(35000-171)

Revised: 12/2019

Colgate-Palmolive Company