

COLGATE TOTAL SF DAILY REPAIR- stannous fluoride paste, dentifrice

Colgate-Palmolive

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™^{SF} Daily Repair 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, flavor, microcrystalline cellulose, sodium citrate, zinc phosphate, cellulose gum, sodium saccharin, cocamidopropyl betaine, propylene glycol, 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 - 144 g 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

NET WT 5.1 OZ (144 g)

Total™^{SF}

WHOLE MOUTH HEALTH

NEW ACTIVE INGREDIENT
STANNOUS FLUORIDE

DAILY
REPAIR
Paste



COLGATE TOTAL SF DAILY REPAIR

stannous fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-173
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: PDC6A3C00X)	
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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:35000-173-93	1 in 1 CARTON	11/01/2018	
1		96 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-173-47	1 in 1 CARTON	11/01/2018	
2		144 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 (001344381)

Establishment

Name	Address	ID/FEI	Business Operations
Colgate-Palmolive		785047999	MANUFACTURE(35000-173)