

COLGATE TOTAL SF 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™ SF 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
- 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, tetrasoium 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 - 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

Total™^{SF}

WHOLE MOUTH HEALTH

NEW ACTIVE INGREDIENT

STANNOUS FLUORIDE

WHITENING

Paste



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

COLGATE TOTAL SF WHITENING

stannous fluoride paste, dentifrice

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:35000-176

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) | |
| 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:35000-176-14 | 1 in 1 CARTON | 11/01/2018 | |
| 1 | | 39 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:35000-176-32 | 1 in 1 CARTON | 11/01/2018 | |
| 2 | | 93 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 3 | NDC:35000-176-48 | 1 in 1 CARTON | 11/01/2018 | |
| 3 | | 136 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 4 | NDC:35000-176-96 | 2 in 1 CARTON | 11/01/2018 | |
| 4 | | 136 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 5 | NDC:35000-176-95 | 1 in 1 CARTON | 11/01/2018 | |
| 5 | | 178 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 6 | NDC:35000-176-78 | 1 in 1 CARTON | 11/01/2018 | |
| 6 | | 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(35000-176) |

Revised: 12/2019

Colgate-Palmolive Company