

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 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 persist 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, Flavor, Sodium Lauryl Sulfate, Microcrystalline Cellulose, Cellulose Gum, Zinc Phosphate, Sodium Citrate, Cocamidopropyl Betaine, Propylene Glycol, Sodium Saccharin, 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 - 181 g Tube Carton

Colgate®

Anticavity, Antigingivitis and Antisensitivity Toothpaste

✓CAVITIES ✓PLAQUE ✓GINGIVITIS ✓ENAMEL ✓TARTAR ✓FRESH BREATH
✓WHITENS ✓SENSITIVITY RELIEF ✓DEEP CLEAN ✓ODOR NEUTRALIZATION

FIGHTS BACTERIA ON TEETH, TONGUE, CHEEKS AND GUMS

Recyclable

Tube

Total

WHOLE MOUTH HEALTH

STANNOUS FLUORIDE

ADVANCED

WHITENING

Paste

NET WT 6.4 OZ (181 g)

Colgate®

Anticavity, Antigingivitis and Antisensitivity Toothpaste

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Total

WHOLE MOUTH HEALTH

STANNOUS FLUORIDE

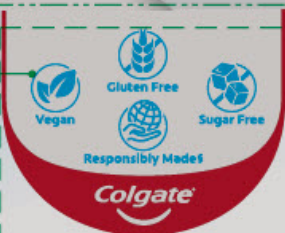
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FIGHTS BACTERIA ON TEETH, TONGUE, CHEEKS AND GUMS



WHOLE MOUTH HEALTH[†] PROTECTS

- ✓ TEETH ✓ TONGUE ✓ CHEEKS ✓ GUMS



PROUDLY MADE BY AMERICAN WORKERS



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

To learn more, visit www.colgatepalmolive.com/responsibly-made



Learn more about our recyclable tube at: colgate.com/goodness

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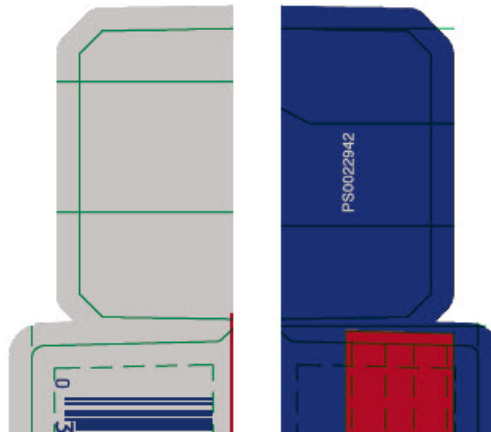
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Questions? 1-800-468-6502



- Helps prevent cavities
- Helps prevent and reduce plaque
- Helps prevent and reduce gingivitis between teeth
- Helps reduce tooth sensitivity
- Helps remove tooth surface stains
- Helps reduce bad breath

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





COLGATE TOTAL SF ADVANCED WHITENING

stannous fluoride paste, dentifrice

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:35000-178 |
| 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: Y607T4G8P9) | |
| 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 (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:35000-178-25 | 1 in 1 CARTON | 05/14/2019 | |
| 1 | | 24.9 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:35000-178-93 | 1 in 1 CARTON | 05/14/2019 | |
| 2 | | 96 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 3 | NDC:35000-178-47 | 1 in 1 CARTON | 05/14/2019 | |
| 3 | | 144 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 4 | NDC:35000-178-65 | 2 in 1 CARTON | 05/14/2019 | |
| 4 | | 144 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 5 | NDC:35000-178-64 | 1 in 1 CARTON | 05/14/2019 | |
| 5 | | 181 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 6 | NDC:35000-178-14 | 1 in 1 CARTON | 05/14/2019 | |
| 6 | | 39.6 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

05/14/2019

Labeler - Colgate-Palmolive Company (001344381)

Revised: 11/2021

Colgate-Palmolive Company