COLGATE TOTAL GUM PROTECTION- 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 Gum Protection

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, Zinc Phosphate, Cellulose Gum, Sodium Citrate, Microcrystalline Cellulose, 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 - Two 136 g Tube Carton

Colgate[®]

Anticavity, Antigingivitis and Antisensitivity Toothpaste

Recyclable

Tube

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

FIGHTS BACTERIA ON TEETH, TONGUE, CHEEKS AND GUMS

2

VALUE

PACK

Total

WHOLE MOUTH HEALTH

12

HR

ANTIBACTERIAL

PROTECTION*

STANNOUS FLUORIDE

GUM PROTECTION Paste TWO 4.8 OZ (136 g) TUBES TOTAL NET WT 9.6 OZ (272 g)

WHOLE MOUTH HEALTH'

"vs_ non-antibacterial fluoride toothpaste serious oral conditions. prevention or treatment of more SAVE P continued use, Not intended for

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MOBKEBS PROUDLY
MADE BY

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

helps prevent gingivitis helps interfere with harmful effects of plaque associated with gingivi builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact

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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.

TOTAL NET WT 9.6 OZ (272 g)

PROTECTION

GUM

ANTIBACTERIAL PROTECTION' STANNOUS FLUORIDE

TWO 4.8 OZ (136 g) TUBES

Drug Facts (continued

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Drug Facts

Recyclable Tube

§To learn more, visit

to gingivitis; fortifies enamel; helps relieve <u>sensitivity with</u> #Helps reduce plaque that leads

www.collgatepalmolive.com/responsibly-made

with twice daily 4 weeks of continued use.

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Questions? 1-800-468-6502















ajebjos





◆ TEETH ◆ TONGUE ◆ CHEEKS ◆ GUMS

Colgate

Colgate



FIGHTS BACTERIA ON TEETH, TONGUE, CHEEKS AND GUMS

✓CAVITIES ✓PLAQUE ✓GINGIVITIS ✓ENAMEL ✓TARTAR ✓FRESH BREATH
✓WHITENS ✓SENSITIVITY RELIEF ✓DEEP CLEAN ✓ODOR NEUTRALIZATION FIGHTS BACTERIA ON TEETH, TONGUE, CHEEKS AND GUMS

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

FIGHTS BACTERIA ON TEETH, TONGUE, CHEEKS AND GUMS

Purposes

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







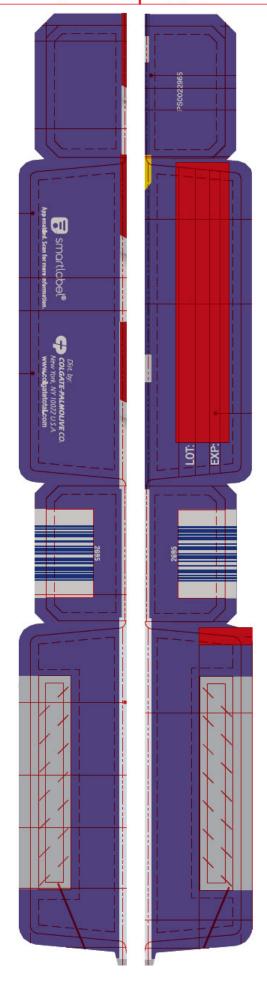
PROTECTION

TWO 4.8 0Z (136 g) TUBES - TOTAL NET WT 9.6 0Z (272 g) Pasto

VALUE

PACK

GUM



COLGATE TOTAL GUM PROTECTION

stannous fluoride paste, dentifrice

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:35000-572

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

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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)
ZINC PHOSPHATE (UNII: 1E2MCT2M62)

CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)

SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)

XANTHAN GUM (UNII: TTV12P4NEE)

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)

SUCRALOSE (UNII: 96K6UQ3ZD4)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

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Color	WHITE	Score
Shape		Size
Flavor	MINT	Imprint Code
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Contains

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:35000-572- 48	1 in 1 CARTON	12/11/2020	12/30/2024
1		136 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-572- 96	2 in 1 CARTON	12/21/2020	12/30/2024
2		136 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:35000-572- 32	1 in 1 CARTON	01/21/2021	12/30/2024
3		93 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	12/11/2020	12/30/2024		

Labeler - Colgate-Palmolive Company (001344381)

Revised: 1/2023 Colgate-Palmolive Company