

## **COLGATE TOTAL GUM PROTECTION- 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.*

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### **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)

# Colgate®

Anticavity, Antigingivitis and Antisensitivity Toothpaste

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- ✓ CAVITIES ✓ PLAQUE ✓ GINGIVITIS ✓ ENAMEL ✓ TARTAR ✓ FRESH BREATH
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Anticavity, Antigingivitis and Antisensitivity Toothpaste

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Questions? 1-800-468-6502

Learn more about our recyclable tube at: [colgate.com/goodness](http://colgate.com/goodness)



To learn more, visit [www.colgatepathtowater.com/responsible-made](http://www.colgatepathtowater.com/responsible-made)

\*vs. non-antibacterial fluoride toothpaste with twice daily 4 weeks of continued use. 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.



PROUDLY MADE BY AMERICAN WORKERS

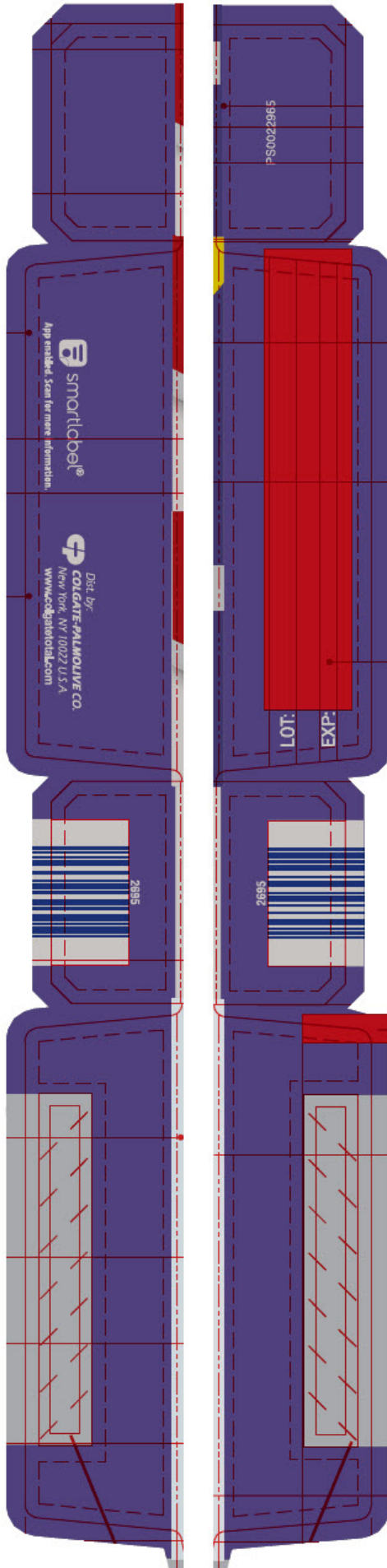
WHOLE MOUTH HEALTH PROTECTS  
TEETH ✓ TONGUE ✓ CHEEKS ✓ GUMS



Colgate Responsibility Made

- Vegan
- Gluten Free
- Sugar Free

\*This glue flap can be extended to accommodate supplier requirements. It must





# COLGATE TOTAL GUM PROTECTION

stannous fluoride paste, dentifrice

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35000-572
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
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)	
ZINC PHOSPHATE (UNII: 1E2MCT2M62)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	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	
1		136 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-572-96	2 in 1 CARTON	12/21/2020	
2		136 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:35000-572-32	1 in 1 CARTON	01/21/2021	
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	

**Labeler** - Colgate-Palmolive (001344381)

## Establishment

Name	Address	ID/FEI	Business Operations
Colgate-Palmolive Company		785047999	ANALYSIS(35000-572) , LABEL(35000-572) , MANUFACTURE(35000-572) , PACK(35000-572)

Revised: 11/2021

Colgate-Palmolive