

## **COLGATE TRIPLE ACTION- sodium 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® Triple Action Fluoride Toothpaste**

### **Drug Facts**

#### **Active ingredient**

Sodium fluoride 0.24% (0.15% w/v fluoride ion)

#### **Purpose**

Anticavity

#### **Use**

helps protect against cavities

#### **Warnings**

**Keep out of reach of children under 6 years of age.** If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

adults and children 2 years of age and older	brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician
children 2 to 6 years	use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)
children under 2 years	ask a dentist or physician

#### **Inactive ingredients**

sorbitol, water, hydrated silica, sodium lauryl sulfate, flavor, PEG-12, tetrasodium pyrophosphate, cocamidopropyl betaine, cellulose gum, sodium saccharin, xanthan gum, titanium dioxide, FD&C blue no. 1, FD&C yellow no. 5

#### **Questions?**

**1-800-468-6502**

*Dist. by:*

**COLGATE-PALMOLIVE**  
COMPANY  
New York 10022

**PRINCIPAL DISPLAY PANEL - 232 g Tube Carton**

*Three Benefits for a Deep Clean*

**Colgate®**

*Fluoride Toothpaste*

*NET WT 8.2 OZ (232 g)*

**Triple**

**Action**

**Original Mint**

**Cavity**

**Protection**

**1**

**Whiter**

**Teeth**

**2**

**Fresh**

**Breath**

**3**

Tres Beneficios para una Limpieza Profunda

# Colgate®

Crema Dental con Flúor

NET WT 8.2 OZ (232 g)

## Triple Action

Menta Original

- 1 Protección Anticaries
- 2 Dientes Más Blancos
- 3 Aliento Fresco

Three Benefits for a Deep Clean

# Colgate®

Fluoride Toothpaste

NET WT 8.2 OZ (232 g)

## Triple Action

Original Mint

- 1 Cavity Protection
- 2 Whiter Teeth
- 3 Fresh Breath

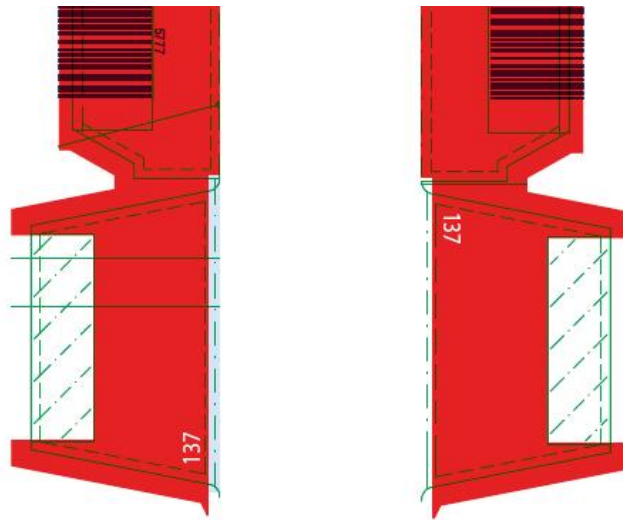
<b>Drug Facts</b>	<b>Active Ingredient</b> Sodium fluoride 0.24% (0.15% W/F fluoride ion)	<b>Purpose</b> Anticavity
<b>Warnings</b>	Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	brush teeth thoroughly, adults and children 2 years of age and older use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing) ask a dentist or physician	
<b>Inactive Ingredients</b>	sorbitol, water, hydroxyethyl cellulose, PEG-20, polyphosphate, cocamidopropyl betaine, cellulosic gum, sodium saccharin, vanillin gum, titanium dioxide, FD&C blue no. 1, FD&C yellow no. 5	
<b>Questions?</b>	1-800-468-6502	
<b>Datos farmacológicos</b>	<b>In ingrediente Activo</b> Propósito Fluoruro de sodio (0.15% por de ion fluoruro) Anticaries	
<b>Uso</b>	Ayuda a prevenir caries	
<b>Advertencias</b>	Mantener fuera del alcance de los niños menores de 6 años. Si se usa más de lo indicado o se accidentalmente se traga, obtener ayuda médica o comunicarse con un Centro de Control de Envenenamiento inmediatamente.	
<b>Instrucciones</b>	Enjuagarse bien los dientes, preferiblemente después de cada comida o por lo menos dos veces al día, o según las indicaciones de un dentista o médico.	
	Niños de 2 a 6 años	usar cantidad del tamaño de una gota algunas veces por un adulto para ayudar a limpiar que sea indicada
	Menores de 2 años	Consulta con el dentista o médico
<b>Ingresantes inactivos</b>	sorbitol, agua, silico hidratado, lauril sulfato de sodio, saborizante, PEG-12, poliolefino de etileno, cocamidopropil betaina, goma celulósica, goma de xantano, vanilina, goma de gualtano, FD&C no. 1, color amarillo FD&C no. 5	
<b>¿Preguntas?</b>	1-800-468-6502	
<a href="http://www.colgate.com">www.colgate.com</a>		
Made in Mexico / Hecho en México		
Dist. by/Por: COLGATE-PALMOLIVE COMPANY New York 10022		

## Triple Action

Unique Formula provides 3 benefits with regular brushing  
Singular Fórmula proporciona 3 beneficios con cepillada regular

- 1 **Cavity Protection** • Helps strengthen your teeth  
**Protección Anticaries** • Ayuda a fortalecer los dientes
- 2 **Whiter Teeth** • Helps remove surface stains  
**Dientes Más Blancos** • Ayuda a remover manchas de la superficie
- 3 **Fresh Breath** • Helps fight against bad breath  
**Aliento Fresco** • Ayuda a combatir el mal aliento





## COLGATE TRIPLE ACTION

sodium fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35000-941
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	220 mg in 1 g
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POLYETHYLENE GLYCOL 600</b> (UNII: NL4J9F21N9)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	BLUE, WHITE, GREEN	<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
1	NDC:35000-941-79	1 in 1 CARTON	12/01/2010	
1		79 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-941-63	1 in 1 CARTON	12/01/2010	
2		85 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:35000-941-69	1 in 1 CARTON	12/01/2010	
3		113 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:35000-941-46	1 in 1 CARTON	12/01/2010	
4		130 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:35000-941-64	1 in 1 CARTON	12/01/2010	
5		181 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:35000-941-82	1 in 1 CARTON	12/01/2010	
6		232 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:35000-941-60	1 in 1 CARTON	12/01/2010	
7		170 g in 1 TUBE; Type 0: Not a Combination Product		
8	NDC:35000-941-48	1 in 1 CARTON	12/01/2010	
8		226 g in 1 TUBE; Type 0: Not a Combination Product		
9	NDC:35000-941-58	1 in 1 CARTON	12/01/2010	
9		70 g in 1 TUBE; Type 0: Not a Combination Product		
10	NDC:35000-941-92	1 in 1 CARTON	12/01/2010	
10		141 g in 1 TUBE; Type 0: Not a Combination Product		
11	NDC:35000-941-99	1 in 1 CARTON	11/09/2020	
11		99 g in 1 TUBE; Type 0: Not a Combination Product		
12	NDC:35000-941-47	1 in 1 CARTON	12/14/2020	
12		133 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	12/01/2010	

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

**Registrant** - Colgate-Palmolive Company (001344381)