

COLGATE TRIPLE ACTION- sodium fluoride paste, dentifrice
Mission Hills S.A de C.V

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® 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**

Drug Facts	Active Ingredient Sodium fluoride 0.24% (0.15% W/W fluoride ion)	Purpose Anticavity
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	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	
Inactive Ingredients	sorbitol, water, hydroxyethyl sodium lauryl sulfate, polyethylene glycol (PEG)-20, pyrophosphate, cocamidopropyl betaine, cellulosic gum, sodium saccharin, vanillin gum, titanium dioxide, FD&C blue no. 1, FD&C yellow no. 5	
Questions?	1-800-468-6502	
Datos farmacológicos	In ingrediente Activo Propósito Fluoruro de sodio (0.15% por de ion fluoruro) Anticaries	
Uso	Ayuda a prevenir caries	
Advertencias	Mantener fuera del alcance de los niños. Si se usa en exceso o se traga accidentalmente, obtener ayuda médica o comunicarse con un Centro de Control de Envenenamiento inmediatamente.	
Instrucciones	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.	
	Usar cantidad del tamaño de una gota de agua para un niño menor de 6 años que sea indicada.	
	Consultar con el dentista o médico.	
Ingresos inactivos	sorbitol, agua, silicato hidratado, lauril sulfato de sodio, estabilizante, PEG-12, profenilo hidroxifenil, cocamidopropil betaina, goma celulósica, goma de xantano, vanilina, óxido de titanio, color azul FD&C no 1, color amarillo FD&C no 5	
¿Preguntas?	1-800-468-6502	
www.colgate.com Made in Mexico / Hecho en México Dist. by/Por: COLGATE-PALMOLIVE COMPANY New York 10022		

Triple Action

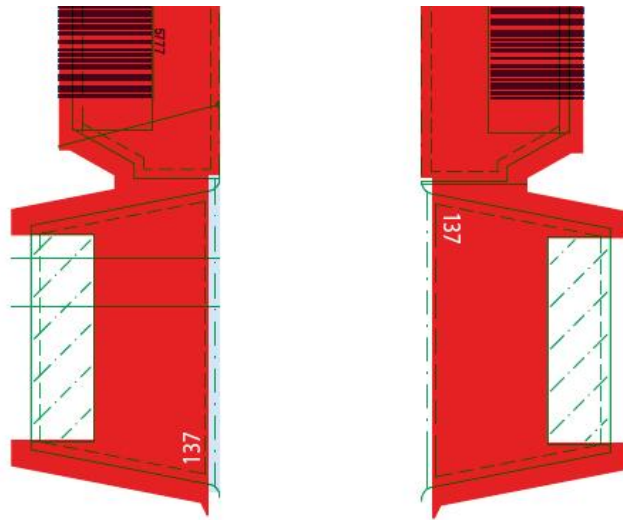
Unique Formula provides 3 benefits with regular brushing
 Singular Fórmula proporciona 3 beneficios con cepillada regular

- 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®





COLGATE TRIPLE ACTION

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65954-536
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color	BLUE, WHITE, GREEN	Score	
Shape		Size	

Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65954-536-79	1 in 1 CARTON		
1		79 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:65954-536-63	1 in 1 CARTON		
2		85 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:65954-536-69	1 in 1 CARTON		
3		113 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:65954-536-46	1 in 1 CARTON		
4		130 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:65954-536-64	1 in 1 CARTON		
5		181 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:65954-536-82	1 in 1 CARTON		
6		232 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:65954-536-60	1 in 1 CARTON		
7		170 g in 1 TUBE; Type 0: Not a Combination Product		
8	NDC:65954-536-48	1 in 1 CARTON		
8		226 g in 1 TUBE; Type 0: Not a Combination Product		
9	NDC:65954-536-58	1 in 1 CARTON		
9		70 g in 1 TUBE; Type 0: Not a Combination Product		
10	NDC:65954-536-92	1 in 1 CARTON		
10		141 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 - Mission Hills S.A de C.V (812312122)

Revised: 10/2015

Mission Hills S.A de C.V