

COLGATE TRIPLE ACTION ORIGINAL MINT FLUORIDE- sodium fluoride paste, dentifrice

Colgate-Palmolive Canada

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
Original Mint**

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

Questions or comments?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

Made in Canada

www.colgate.com

PRINCIPAL DISPLAY PANEL - 130 g Tube

Colgate®
Fluoride Toothpaste

NET WT 4.6 OZ (130 g)

**Triple
Action**

Original Mint

Cavity Protection

1

Whiter Teeth


2

Fresh Breath

3

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¿Preguntas? ¿Comentarios? 1-800-468-6502




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Colgate®
Fluoride Toothpaste Crema Dental con Flúor

NET WT 4.6 OZ (130 g)



1
Cavity Protection
Protección Anticaries

2
Whiter Teeth
Dientes Más Blancas

3
Fresh Breath
Aliento Fresco

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Anticavity

Ingrediente Activo
Sodium fluoride 0.24% (0.15% w/v fluoride ion).....

Uso Ayuda a prevenir caries

Advertencias Mantener fuera del alcance de niños menores de 6 años. Si se ingiere accidentalmente una cantidad mayor a la usada para cepillarse, obtener atención médica o comunicarse con un Centro de Control de Envenenamiento inmediatamente.

Instrucciones • Adultos y niños de 2 años y mayores: cepillarse 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 supervisados por un adulto para minimizar que sea ingerida. • Menores de 2 años: Consulte con su dentista o médico.

Ingredientes inactivos sorbitol, agua, sílica hidratada, Polietilén Glicol 600, laurilsulfato de sodio, sabor, goma de celulosa, pirofosfato tetrasodio, cocamidopropil betaina, sacarina sódica, dióxido de titanio, FD&C azul no. 1, FD&C amarillo no. 5

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COLGATE TRIPLE ACTION ORIGINAL MINT FLUORIDE

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51442-536
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Sodium Fluoride	2.4 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Sorbitol (UNII: 506T60A25R)	
Water (UNII: 059QF0KO0R)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Polyethylene Glycol (UNII: 3WJQ0SDW1A)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Carboxymethylcellulose Sodium (UNII: K679OBS311)	
Sodium Pyrophosphate (UNII: O352864B8Z)	
Cocamidopropyl Betaine (UNII: 5OCF3011KX)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
FD&C Blue No. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	BLUE, WHITE (Stripe) , GREEN (Stripe)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51442-536-46	1 in 1 CARTON		
1		130 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	11/17/2010	

