

COLGATE DOUBLE FRESH- sodium 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® Double Fresh

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, Blue 1, Titanium Dioxide.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE
COMPANY

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 170 g Tube Carton

Colgate®
Anticavity fluoride
toothpaste

Doble
Frescura

MAXIMUM CAVITY PROTECTION†

6.0 OZ (170 g)

Colgate®

Crema dental anticaries con flúor

Doble Frescura

MÁXIMA PROTECCIÓN ANTICARIES*

6.0 OZ (170 g)

Colgate®

Crema dental anticaries con flúor Anticavity fluoride toothpaste

Doble Frescura

MÁXIMA PROTECCIÓN ANTICARIES*
MAXIMUM CAVITY PROTECTION*

6.0 OZ (170 g)

Drug Facts

Active Ingredient: Purpose: Fluoride 0.24% (0.15% w/w Fluoride Ion) - Anticavity

Use: helps protect against cavities

Warnings: Keep out of reach of children under 6 years of age. If more than used for brushing to avoid injury to tongue, throat, lips, or contact with eyes. For use only in contact with toothbrush.

Directions: 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, Blue 1, Titanium Dioxide.

Questions? 1-800-468-6502

Datos Farmacológicos

Ingrediente activo: Propósito: Flúor de 0,24% (0,15% proteína fluoruro) - Anticaries

Uso: ayuda a prevenir caries

Advertencias: Mantener fuera del alcance de los niños menores de 6 años. Si se usa en exceso puede causar irritación a la lengua, la garganta o los ojos. Usar solo en contacto con el cepillo de dientes. Evitar el contacto con la boca o con los ojos.

Indicaciones: cepillarse los dientes, preferiblemente después de cada comida o por lo menos dos veces al día, o según las indicaciones de un dentista o médico

Para niños de 2 a 6 años: usar una cantidad de pasta de dientes del tamaño de un grano de arroz y supervisar al niño para minimizar el riesgo de tragar o ingerir la pasta de dientes

Ingredientes Inactivos: Sorbitol, Agua, Hidroxido de Silicio, Sulfato de Lauril Sódico, Polipropileno, Glicerina, Polietileno Glicol, Polifosfato de Sodio, Xantano, Celulosa, Sacarina Sódica, Goma de Xantano, Azul 1, Dióxido de Titanio.

Preguntas? 1-800-468-6502

www.colgate.com

Made in Mexico / Hecho en México

DIST. BY/POR: COLGATE-PALMOLIVE COMPANY, New York, NY 10022 U.S.A.

GLUTEN FREE SIN GLUTEN

Colgate®

Doble Frescura

MÁXIMA PROTECCIÓN ANTICARIES*
MAXIMUM CAVITY PROTECTION*

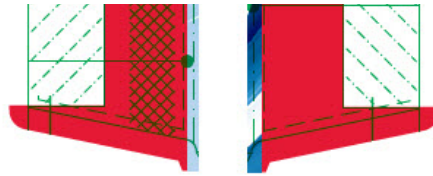
¡Doble Frescura para toda la familia!
Double Fresh for the Whole Family!



¡Hemos cambiado a un tubo reciclable! Más información en www.colgate.com/vea/otnos
We've switched to a recyclable tube! Learn more at www.colgate.com/vea/otnos
Recicle el tubo viejo con la tapa puesta / Recycle empty tube with cap on

Ingrediente activo anticaries máximo permitido por la FDA
*maximum FDA allowed anticavity active ingredient





COLGATE DOUBLE FRESH

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-746
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	2.4 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	567 mg in 1 g
WATER (UNII: 059QF0K00R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE, WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-746-60	1 in 1 CARTON	11/24/2021	

1		170 g in 1 TUBE; Type 0: Not a Combination Product	
2	NDC:35000-746-30	3 in 1 CARTON	11/24/2021
2		170 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	11/24/2021	

Labeler - Colgate-Palmolive Company (001344381)

Revised: 11/2021

Colgate-Palmolive Company