COLGATE RE RENEW- 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® RE renew

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 the child's brushing and rinsing (to minimize swallowing)	
children under 2 years	ask a dentist or physician	

Inactive ingredients

Water, Sorbitol, Hydrated Silica, Calcium Pyrophosphate, PEG-12, Tetrapotassium Pyrophosphate, Sodium Lauryl Sulfate, Flavor, Potassium Hydroxide, Cellulose Gum,

Phosphoric Acid, Xanthan Gum, Cocamidopropyl Betaine, Sodium Saccharin.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE CO.

New York, NY 10022 U.S.A

PRINCIPAL DISPLAY PANEL - 107 g Tube Label

Colgate®

re:

re:new

whitening

fresh mint & micro-polishers

anticavity fluoride toothpaste

NET WT 3.8 OZ (107 g)

P18133472





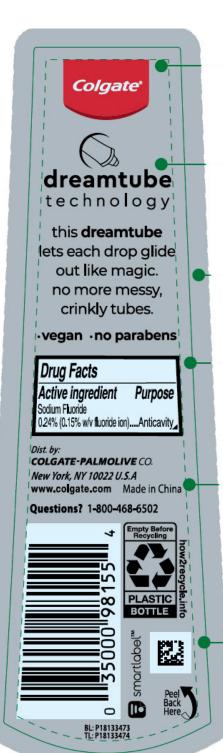
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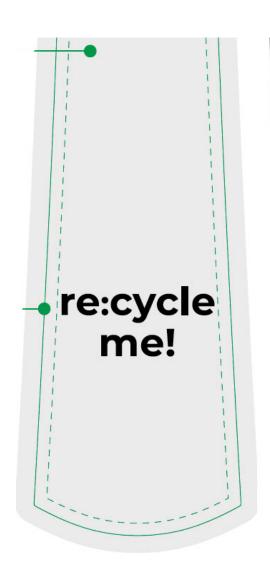
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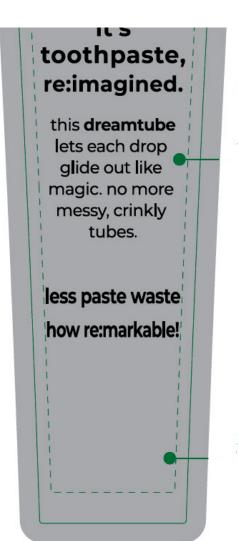
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COLGATE RE RENEW

sodium fluoride paste, dentifrice

D		I C	-
Prod	uct	Inform	nation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:35000-744

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)

Basis of Strength
FLUORIDE ION

1.1 mg in 1 g

Inactive Ingredients

Ingredient Name

WATER (UNII: 059QF0KO0R)

SORBITOL (UNII: 506T60A25R)

HYDRATED SILICA (UNII: Y607T4G8P9)

CALCIUM PYROPHOSPHATE (UNII: X69NU20D19)

POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)

POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)			
PHOSPHORIC ACID (UNII: E4GA8884NN)			
XANTHAN GUM (UNII: TTV12P4NEE)			
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			

Product Characteristics		
Color	WHITE	Score
Shape		Size
Flavor	MINT	Imprint Code
Contains		

ı	Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1	NDC:35000-744- 59	107 g in 1 TUBE; Type 0: Not a Combination Product	08/07/2021	

Marketing Information				
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part355	08/07/2021		

Labeler - Colgate-Palmolive Company (001344381)

Revised: 7/2021 Colgate-Palmolive Company