## COLGATE RE REENERGIZE- sodium fluoride gel, 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.

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#### Colgate® RE reenergize

#### **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**

Sorbitol, Water, Hydrated Silica, Sodium Lauryl Sulfate, Flavor, PEG-12, Cellulose Gum, Cocamidopropyl Betaine, Sodium Saccharin, Propylene Glycol, Pyrus Communis (Pear)

Fruit Extract, Red 40.

#### **Questions?**

1-800-468-6502

Dist. by:

**COLGATE-PALMOLIVE** CO.

New York, NY 10022 U.S.A

#### PRINCIPAL DISPLAY PANEL - 107 g Tube Label

 $\text{Colgate}^{\text{\circledR}}$ 

re:

re:energize

revitalizes breath

fresh mint & citrus

anticavity fluoride toothpaste

NET WT 3.8 OZ (107 g)

P18133467







#### Use

helps protect against cavities

#### Warnings

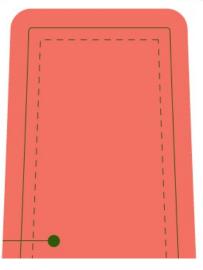
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#### **COLGATE RE REENERGIZE**

sodium fluoride gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-743
Route of Administration	DENTAL		

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION 1.1 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
SORBITOL (UNII: 506T60A25R)			
WATER (UNII: 059QF0KO0R)			
HYDRATED SILICA (UNII: Y6O7T4G8P9)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)			
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)			

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PYRUS COMMUNIS WHOLE (UNII: 80UKV9Y4B3)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

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

ı	Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1	NDC:35000-743- 59	107 g in 1 TUBE; Type 0: Not a Combination Product	08/07/2021	

Marketing Information			
Marketing Category	Application Number or Monograph 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