

COLGATE RE REFRESH- 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.

Colgate® RE refresh

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	ask a dentist or

years

|physician

Inactive ingredients

Sorbitol, Water, Hydrated Silica, Sodium Lauryl Sulfate, Flavor, PEG-12, Cellulose Gum, Cocamidopropyl Betaine, Sodium Saccharin, Algin, Blue 1.

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:fresh

freshens

mouth

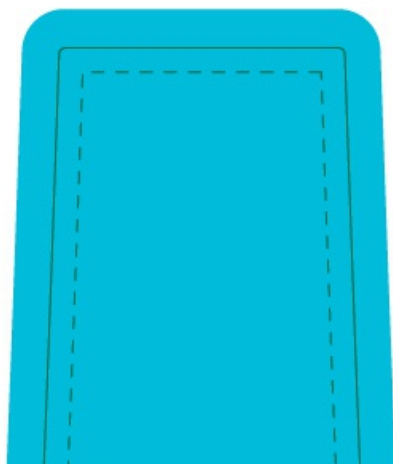
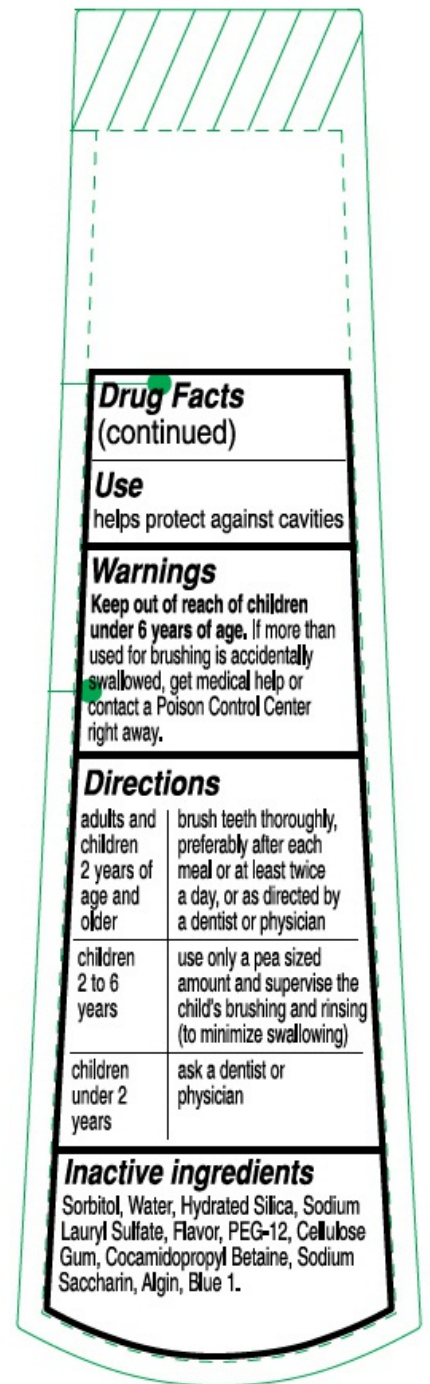
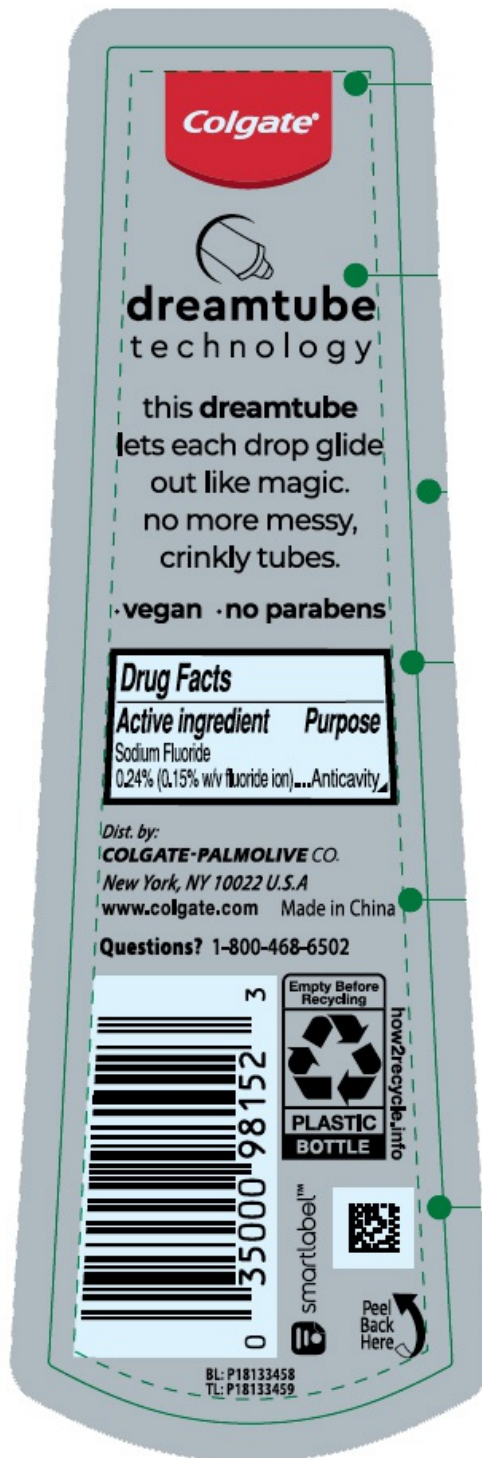
fresh mint

& wintergreen

anticavity fluoride toothpaste

NET WT 3.8 OZ (107 g)

P18133457





COLGATE RE REFRESH

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-741
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	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: K679OBS311)

COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

ALGINIC ACID (UNII: 8C3Z4148WZ)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-741-59	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

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