

COLGATE RE REVIVE- 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 revive

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, Charcoal Powder, Blue 1, 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

Colgate®

re:

re:vive

polishes

teeth

fresh mint

& charcoal

anticavity fluoride toothpaste

NET WT 3.8 OZ (107 g)

P18133452

Colgate®

re:
re:vive

polishes
teeth

fresh mint
& charcoal

ant cavity fluoride toothpaste

NET WT 3.8 OZ (107 g)

P18133452

Colgate®



dreamtube
technology

this **dreamtube**
lets each drop glide
out like magic.
no more messy,
crinkly tubes.

·vegan ·no parabens

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www.colgate.com Made in China

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Peel Back Here

BL: P18133453
TL: P18133454

Drug Facts
(continued)

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Directions

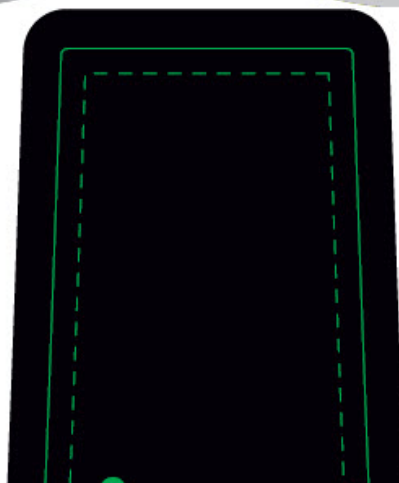
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COLGATE RE REVIVE

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-740
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: Y607T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	

CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	BLACK	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-740-59	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