

COLGATE RE VARIETY PACK- sodium fluoride
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: Variety Pack

re:vive

Drug Facts

Active ingredient

Sodium Fluoride

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

re:pair

Drug Facts

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Sodium Fluoride

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Inactive ingredients

Sorbitol, Water, Hydrated Silica, Sodium Lauryl Sulfate, Flavor, PEG-12, Cellulose Gum, Cocamidopropyl Betaine, Sodium Saccharin, Blue 1, Yellow 5.

Questions?

1-800-468-6502

re:energize

Drug Facts

Active ingredient

Sodium Fluoride

Use

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Warnings

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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

re:fresh

Drug Facts

Active ingredient

Sodium Fluoride

Use

helps protect against cavities

Warnings

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Directions

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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, Algin, Blue 1.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE CO.

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - Kit Blister Pack

Colgate®

dreamtube
technology

4

PACK

- glides on smooth
- helps you squeeze out every drop!

FOUR 3.8 OZ (107 g) TUBES*
TOTAL NET WT 15.2 OZ (428 g)

PS0025725

Colgate®


dreamtube
technology

4
PACK

- glides on smooth
- helps you squeeze out every drop!

FOUR 3.8 OZ (107 g) TUBES* TOTAL NET WT 15.2 OZ (428 g)

PS0025725

Colgate®


dreamtube
technology

this dreamtube lets each
drop glide out like magic.



no more messy, crinkly tubes.

vegan, no parabens

re:vive

Drug Facts	
Active ingredient	Purpose
Sodium Fluoride	
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	

re:pair

Drug Facts	
Active ingredient	Purpose
Sodium Fluoride	
Use helps protect against cavities	
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Inactive ingredients Sorbitol, Water, Hydrated Silica, Sodium Lauryl Sulfate, Flavor, PEG-12, Cellulose Gum, Cocamidopropyl Betaine, Sodium Saccharin, Blue 1, Yellow 5.	
Questions? 1-800-468-6502	

re:energize

Drug Facts	
Active ingredient	Purpose
Sodium Fluoride	
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, Pinus Commisus (Pearl Fruit Extract, Red 40.	
Questions? 1-800-468-6502	

re:refresh

Drug Facts	
Active ingredient	Purpose
Sodium Fluoride	
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.	
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Inactive ingredients Sorbitol, Water, Hydrated Silica, Sodium Lauryl Sulfate, Flavor, PEG-12, Cellulose Gum, Cocamidopropyl Betaine, Sodium Saccharin, Amino Acids, Blue 1.	
Questions? 1-800-468-6502	



Dist. by:
COLGATE-PALMOLIVE CO.
New York, NY 10022 U.S.A.
www.colgate.com

Questions?
1-800-468-6502
Made in China



COLGATE RE VARIETY PACK

sodium fluoride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-745
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-745-93	1 in 1 BLISTER PACK	10/01/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	107 g
Part 2	1 TUBE	107 g
Part 3	1 TUBE	107 g
Part 4	1 TUBE	107 g

Part 1 of 4

COLGATE RE REENERGIZE

sodium fluoride gel, dentifrice

Product Information

Item Code (Source) NDC:35000-743

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)	
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			

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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH	part 255	10/01/2021	

Part 2 of 4**COLGATE RE REPAIR**

sodium fluoride gel, dentifrice

Product Information**Item Code (Source)** NDC:35000-742**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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-742-59	107 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	10/01/2021	

Part 3 of 4

COLGATE RE REFRESH

sodium fluoride gel, dentifrice

Product Information

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
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1	NDC:35000-741-59	107 g in 1 TUBE; Type 0: Not a Combination Product	
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	10/01/2021	

Part 4 of 4

COLGATE RE REVIVE

sodium fluoride gel, dentifrice

Product Information

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: Y6O7T4G8P9)	
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: 2P3VWUJ3H10)	
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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	10/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	10/01/2021	

Labeler - Colgate-Palmolive Company (001344381)

Revised: 9/2021

Colgate-Palmolive Company