

**COLGATE ENAMEL HEALTH MINERAL REPAIR- potassium nitrate and 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.*

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**Colgate® Enamel Health™ Mineral Repair**

<b>Active ingredients</b>	<b>Purpose</b>
Potassium nitrate 5%	Antisensitivity
Sodium fluoride 0.24% (0.15% w/v fluoride ion)	Anticavity

**Uses**

- builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact
- helps protect against cavities

**Warnings**

- **When using this product**, if pain/sensitivity still persists after 4 weeks of use, please visit your dentist.
- **Stop use and ask a dentist** if the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.
- **Keep out of reach of children.** If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Adults and children 12 years of age and older: Apply at least a 1-inch strip of the product onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute twice a day (morning and evening) or as recommended by a dentist or physician. Make sure to brush all sensitive areas of the teeth.
- Children under 12 years: Consult a dentist or physician.

**Inactive ingredients**

water, sorbitol, hydrated silica, glycerin, PEG-12, tetrasodium pyrophosphate, flavor, sodium lauryl sulfate, microcrystalline cellulose, zinc phosphate, cellulose gum, sodium saccharin, cocamidopropyl betaine, xanthan gum, tricalcium phosphate, mica, titanium dioxide, FD&C blue no. 1

**Questions?**

**1-800-468-6502**

**www.colgate.com**

*Dist. by:*

**COLGATE-PALMOLIVE COMPANY**

*New York, NY 10022*

**PRINCIPAL DISPLAY PANEL - 113 g Tube Label**

**Colgate®**

*Anticavity & Antisensitivity Toothpaste*

**ENAMEL  
HEALTH™**

**MINERAL  
REPAIR**

**HELPS REPAIR  
WEAKENED ENAMEL  
WITH VITAL MINERALS**

- ENAMEL EROSION
- SENSITIVITY
- WHITENS
- CAVITIES
- FRESHENS

MINT BURST  
*gel*

**NET WT 4.0 OZ (113 g)**



**Colgate**  
Anticavity & Antisensitivity Toothpaste

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## COLGATE ENAMEL HEALTH MINERAL REPAIR

potassium nitrate and sodium fluoride paste, dentifrice

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-209
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	50 mg in 1 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ZINC PHOSPHATE (UNII: 1E2MCT2M62)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

### 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:35000-209-69	1 in 1 CARTON	10/12/2015	
1		113 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 NOT FINAL	part356	10/12/2015	

**Labeler** - Colgate-Palmolive Company (001344381)

### Establishment

Name	Address	ID/FEI	Business Operations
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Colgate-Palmolive		785047999	MANUFACTURE(35000-209)
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Revised: 12/2019

Colgate-Palmolive Company