

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.

Colgate® Enamel Health™ Mineral Repair

<i>Active ingredients</i>	<i>Purpose</i>
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)

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Anticavity & Antisensitivity Toothpaste

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• P9907377 2081

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: 059QF0KO0R)				
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: 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:35000-209-69	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

Colgate-Palmolive		785047999	MANUFACTURE(35000-209)
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