

COLGATE ENAMEL RENEWAL SENSITIVITY- 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 Renewal Sensitivity

Drug Facts

Active ingredients	Purpose
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, Zinc Phosphate, Cellulose Gum, Microcrystalline Cellulose, Sodium Saccharin, Cocamidopropyl Betaine, Xanthan Gum, Red 40.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE CO.

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 85 g Tube Carton

Colgate®

Anticavity Toothpaste for Sensitive Teeth

NEW

ENAMEL

RENEWAL

REPAIRS

ENAMEL

BY REVERSING

MICRO-DAMAGE*

MINERAL

COMPLEX

SENSITIVITY

NET WT 3.0 OZ (85 g)

PASTE



COLGATE ENAMEL RENEWAL SENSITIVITY

potassium nitrate and sodium fluoride paste, dentifrice

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:35000-225

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

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"This glue flap can be extended to accommodate supplier requirements. It must comply with the CP Quality gluing standards."

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:Q80VPU4080)	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)	
ZINC PHOSPHATE (UNII: 1E2MCT2M62)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-225-63	1 in 1 CARTON	11/15/2021	12/31/2024
1		85 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	11/15/2021	12/31/2024

