**COLGATE ENAMEL RENEWAL WHITENING- 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 Renewal Whitening**

***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, Blue 1.

**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

WHITENING

NET WT 3.0 OZ (85 g)
PASTE


# COLGATE ENAMEL RENEWAL WHITENING

potassium nitrate and sodium fluoride paste, dentifrice

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:35000-226 |

| | |
|---|---|
| **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) | |
| **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 BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | MINT | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:35000-226-63 | 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 |

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

Revised: 11/2021

Colgate-Palmolive Company