# COLGATE SENSITIVE COMPLETE PROTECTION- 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<sup>®</sup> Sensitive Complete Protection

#### **Drug Facts**

Active ingredients	Purpose
Potassium nitrate 5%	Antisensitivity
Sodium fluoride 0.24% (0.14% w/v fluoride ion)	Anticavity

#### Use

- 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, Glycerin, Hydrated Silica, Sorbitol, PEG-12, Tetrapotassium Pyrophosphate, PVM/MA Copolymer, Flavor, Sodium Lauryl Sulfate, Poloxamer 407, Sodium Hydroxide, Sodium Saccharin, Cellulose Gum, Xanthan Gum, Titanium Dioxide

#### Questions?

#### 1-800-468-6502

Dist. by: **COLGATE-PALMOLIVE** COMPANY New York, NY 10022 U.S.A.

# PRINCIPAL DISPLAY PANEL - 170 g Tube Carton

Colgate<sup>®</sup> Anticavity Toothpaste for Sensitive Teeth

MAXIMUM STRENGTH\*

Sensitive

COMPLETE PROTECTION

8 BENEFITS

©SENSITIVITY ©TARTAR ©FRESHENS ©CAVITIES ©ENAMEL ©PLAQUE<sup>†</sup> ©WHITENS ©GUMS<sup>†</sup>

NET WT 6.0 OZ (170 g)

MINT CLEAN paste

#### COLGATE SENSITIVE COMPLETE PROTECTION potassium nitrate and sodium fluoride paste, dentifrice **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:35000-024 **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) GLYCERIN (UNII: PDC6A3C0OX) HYDRATED SILICA (UNII: Y6O7T4G8P9) SORBITOL (UNII: 506T60A25R) POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9) POTASSIUM PYROPHO SPHATE (UNII: B9W4019H5G) BUTYL ESTER OF METHYL VINYL ETHER/MALEIC ANHYDRIDE COPOLYMER (125000 MW) (UNII: 389H2R62BD) **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) POLOXAMER 407 (UNII: TUF2IVW3M2) SODIUM HYDRO XIDE (UNII: 55X04QC32I) SACCHARIN SODIUM (UNII: SB8ZUX40TY) CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311) XANTHAN GUM (UNII: TTV12P4NEE) TITANIUM DIO XIDE (UNII: 15FIX9V2JP) **Product Characteristics** Color WHITE Score Shape Size MINT Flavor Imprint Code Contains

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-024-60	1 in 1 CARTON	02/25/2019	
1		170 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-024-34	2 in 1 CARTON	0 2/25/20 19	
2		170 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:35000-024-33	1 in 1 CARTON	11/13/2018	

3 30	6.8 g in 1 TUBE; Type 0: Not a Co	mbination Product		
Marketing Information				
Marketing Categor	y Application Number or	Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT F	FINAL part356		11/13/2018	

# Labeler - Colgate-Palmolive Company (001344381)

# Establishment

Name	Address	ID/FEI	Business Operations
Colgate-Palmolive		785047999	MANUFACTURE(35000-024)

Revised: 12/2019

Colgate-Palmolive Company