# COLGATE SENSITIVE PREVENT AND REPAIR- potassium nitrate and sodium fluoride paste, dentifrice Colgate-Palmolive

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<sup>®</sup> Sensitive Prevent & Repair

#### **Drug Facts**

Active ingredients	Purpose
Potassium Nitrate 5%	Antisensitivity
Sodium Fluoride 0.24% (0.14% 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, Glycerin, Hydrated Silica, Sorbitol, PEG-12, PVM/MA Copolymer, Sodium Lauryl Sulfate, Flavor, Trisodium Phosphate, 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

ADVANCED DUAL ACTION FORMULA HELPS || PREVENT SENSITIVITY || REPAIR WEAKENED ENAMEL

MAXIMUM STRENGTH\*

Sensitive

PREVENT & REPAIR + WHITENING

NET WT 6.0 OZ (170 g) GENTLE MINT paste



strengthen enamel with fluoride GLUTEN FREE

sensations are carried

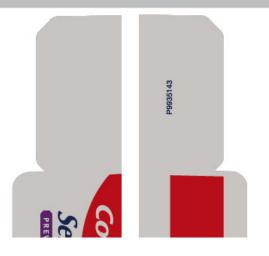
down these channels

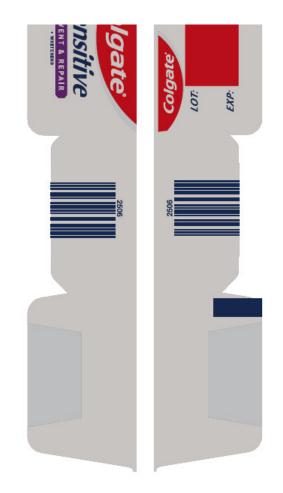
directly to the nerves,

causing pain.

\* Maximum strength FDA allowed antisensitivity active ingredient







DLGATE SENSITIVE PREVENT AND REPAIR
-------------------------------------

potassium nitrate and sodium fluoride paste, dentifrice

<b>Product Information</b>					
Product Type	HUMAN OTC DRUG Item Code (Source) NDC:35000				00-128
Route of Administration	DENTAL				
Active Ingredient/Active Mo	ety				
Ing	gredient Name		Basis of S	trength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844) POTASSIUM NITRATE					
PUTASSIUM NITRATE (UNII. RU45A	.5102) (11110111 1011 - 0111.152	12044)	101/101/101/11		50 mg in 1 g
SODIUM FLUORIDE (UNII: 8ZYQ1474	, (	,	FLUORIDE IO	N	1.1 mg in 1 g
	, (	,		N	0 0
SO DIUM FLUORIDE (UNII: 8 ZYQ 1474	, (	VPU408O)		N	0 0
SO DIUM FLUORIDE (UNII: 8 ZYQ 1474	W7) (FLUORIDE ION - UNII:Q80	VPU408O)		N	1.1 mg in 1 g
SODIUM FLUORIDE (UNII: 8ZYQ1474	W7) (FLUORIDE ION - UNII:Q80	VPU408O)		N	1.1 mg in 1 g
SO DIUM FLUORIDE (UNII: 8 ZYQ1474 Inactive Ingredients WATER (UNII: 059QF0K00R)	W7) (FLUORIDE ION - UNII:Q80 Ingredient Name	VPU408O)		N	1.1 mg in 1 g
SO DIUM FLUO RIDE (UNII: 8 ZYQ1474 Inactive Ingredients WATER (UNII: 059QF0K00R) GLYCERIN (UNII: PDC6A3C0OX)	W7) (FLUORIDE ION - UNII:Q80 Ingredient Name	VPU408O)		N	1.1 mg in 1 g
SO DIUM FLUORIDE (UNII: 8 ZYQ1474 Inactive Ingredients WATER (UNII: 059QF0K00R) GLYCERIN (UNII: PDC6A3C00X) HYDRATED SILICA (UNII: Y607T4G8	:W7) (FLUORIDE ION - UNII:Q80 Ingredient Name P9)	VPU408O)		N	1.1 mg in 1 g
SO DIUM FLUORIDE (UNII: 8 ZYQ1474 Inactive Ingredients WATER (UNII: 059QF0K00R) GLYCERIN (UNII: PDC6A3C0OX) HYDRATED SILICA (UNII: Y607T4G8 SORBITOL (UNII: 506T60A25R)	P9) I: NL4J9F21N9)	VPU408O)		N	1.1 mg in 1 g

SODIUM LAURYL SU	LFATE (U	INII: 368GB5141J)						
POLOXAMER 407 (U	NII: TUF2F	VW3M2)						
SO DIUM HYDRO XIDE	E (UNII: 55	X04QC32I)						
SACCHARIN SO DIUM	(UNII: SB	8ZUX40TY)						
CARBOXYMETHYLC	ELLULOS	SE SODIUM, UNSPEC	IFIED FO	<b>RM</b> (UNII: K67	90B	S311)		
XANTHAN GUM (UNII	TTV12P4	NEE)						
TITANIUM DIO XIDE (	UNII: 15FE	X9 V2JP)						
Product Characte	ristics							
Color	1154165	WHITE		Score				
Shape		WILLE		Size				
Flavor					•			
Contains				Imprint Code				
Packaging								
# Item Code		Package Description		Ma	rketing Start Date	Marketing I	End Date	
<b>1</b> NDC:35000-128-60	1 in 1 CA				10/2	0/25/2019		
1	170 g in 1 TUBE; Type 0: Not a Combination Product							
Marketing Info	ormati	ion						
Marketing Categ				ion	Marketing Start Date	Marketing	End Date	
OTC MONOGRAPH NO	T FINAL					10/25/2019		

## Labeler - Colgate-Palmolive (001344381)

## Establishment

Name	Address	ID/FEI	Business Operations
Colgate-Palmolive		785047999	MANUFACTURE(35000-128)

Revised: 12/2019

Colgate-Palmolive