COLGATE SENSITIVE PRO RELIEF WHITENING- sodium fluoride and potassium nitrate 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[®] Sensitive Pro Relief™ Whitening 4.0oz Fluoride Toothpaste

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

	apply at least a 1-inch strip of the product onto a
adults and children	soft bristle toothbrush. Brush teeth thoroughly for
12 years of age and	at least 1 minute twice a day (morning and evening)
older	or as recommended by a dentist or physician.
	Make sure to brush all sensitive areas of the teeth.
children under 12	acroult a doutiet or physician
years	consult a dentist or physician

Inactive ingredients

water, hydrated silica, glycerin, sorbitol, PEG-12, PVM/MA copolymer, sodium lauryl sulfate, flavor, poloxamer 407, trisodium phosphate, sodium hydroxide, cellulose gum, sodium saccharin, xanthan gum, titanium dioxide

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 113 g Tube Carton

 $Colgate^{\mathbb{R}}$

Fluoride Toothpaste for Sensitive Teeth

24/7

Protection*

Sensitive Pro-Relief™ CLINICALLY PROVEN sensitivity relief

NET WT 4.0 OZ (113 g)

+ WHITENING

Cool Mint



24/7 Protection*



Sensitive Pro_'Relief'

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are the source of

Drug Facts (continued)

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

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Penetrates to the nerve for long-lasting relief!*

Where does sensitive tooth pain come from?

Receding gums and damage to your enamel can expose thousands of microscopic channels which lead to your

tooth's nerve center. When your teeth make contact with something hot, cold or sweet, sensations are carried down these channels directly to the nerves, causing pain.

A lasting "protective shield" helps prevent sensitivity pain from returning. Exposed dentin



How does Colgate Sensitive Pro-Relief® + Whitening toothpaste work?

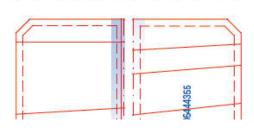
Colgate Sensitive Pro-Relief® is a clinically proven formula that works fast, within 2 weeks, to provide relief to the nerve and builds a protective shield to help

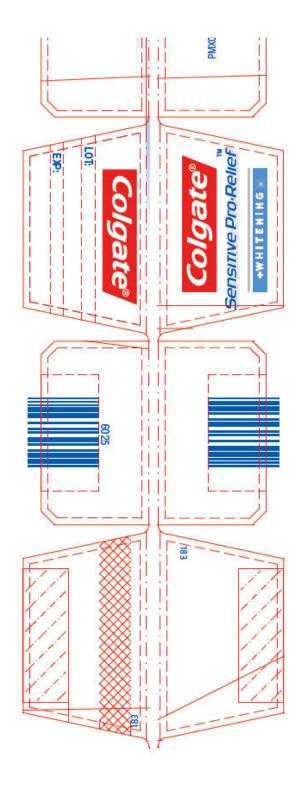
prevent painful sensitivity flare-ups when used as directed.

- · Provides fast-acting and long-lasting relief with regular use.
- Effectively removes stains, helping restore the natural whiteness of your teeth.



*with continued use





COLGATE SENSITIVE PRO RELIEF WHITENING

Ingredient Name

sodium fluoride and potassium nitrate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-943
Route of Administration	DENTAL		
Active Ingredient/Active Moiety			

Basis of Strength

Strength

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	1.1 mg in 1 g
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	50 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
HYDRATED SILICA (UNII: Y6O7T4G8P9)	180 mg in 1 g
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
BUTYL ESTER OF METHYL VINYL ETHER/MALEIC ANHYDRIDE COPOLYMER (125000 MW) (UNII: 389H2R62BD)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PHOSPHATE ION (UNII: NK08 V8 K8 HR)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679 OBS 311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:35000-943-69	1 in 1 CARTON	09/06/2010		
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	09/06/2010		

Labeler - Colgate-Palmolive Company (001344381)