

COLGATE SENSITIVE PLUS 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.

Colgate® Sensitive plus Whitening

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, Poloxamer 407, Trisodium Phosphate, Sodium Hydroxide, Sodium Saccharin, Cellulose Gum, Xanthan Gum, Titanium Dioxide, Blue 1.

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®

Anticavity Toothpaste for Sensitive Teeth

MAXIMUM STRENGTH*

Sensitive

RELIEVES & WHITENS

- ▣ CLINICALLY PROVEN SENSITIVITY RELIEF
- ▣ SUPERIOR STAIN REMOVAL†

NET WT 6.0 OZ (170 g)

WHITENING

FRESH MINT

gel

Colgate®

Anticavity Toothpaste for Sensitive Teeth

MAXIMUM STRENGTH™

Sensitive



RELIEVES & WHITENS
 ✓ CLINICALLY PROVEN SENSITIVITY RELIEF
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WHITENING

FRESH MINT

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Turning off your water while brushing your teeth can save up to 4 gallons of water each time you brush!



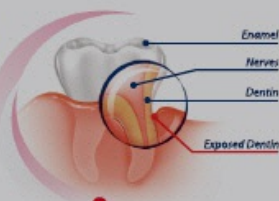
Dist. by COLGATE-PALMOLIVE COMPANY
 New York, NY 10022 U.S.A.
 www.colgatesensitive.com

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.

Colgate® Sensitive Whitening is formulated for daily use.

- ✓ 24/7 sensitivity protection with twice daily brushing
- ✓ Superior stain removal, helping to restore the natural whiteness of your teeth†

GLUTEN FREE



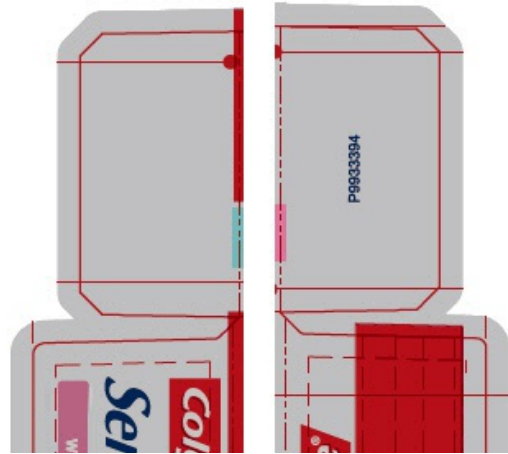
How does Colgate® Sensitive Whitening work?

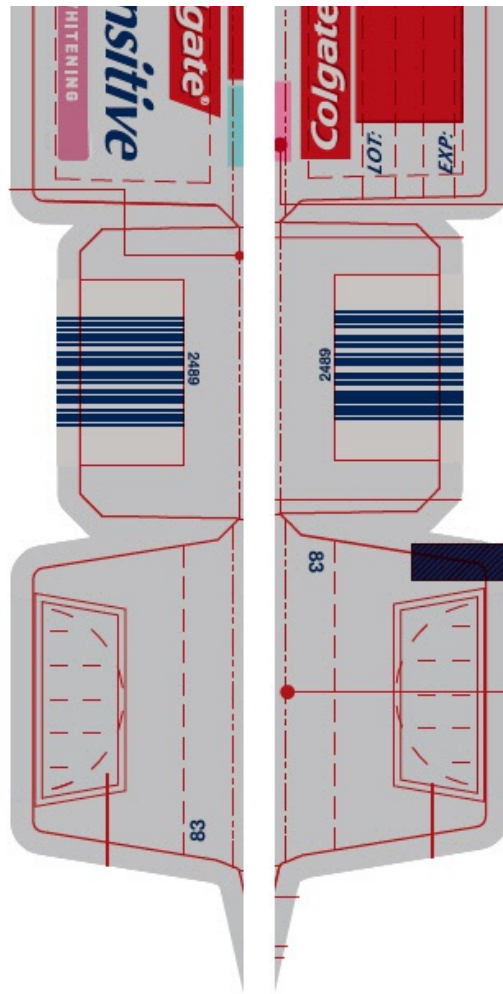
Colgate® Sensitive Whitening contains potassium nitrate, clinically proven to soothe the nerves in exposed dentin. With regular use, it provides long-lasting sensitivity relief and removes surface stains to help keep teeth whiter and brighter.*
 * Maximum strength FDA allowed antisensitivity active ingredient † With regular brushing vs. non-whitening toothpaste

smartLabel™
 visit smartlabel.colgate.com for ingredient information



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





COLGATE SENSITIVE PLUS WHITENING

potassium nitrate and sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-023
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: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
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)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE (UNII: B70850QPHR)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-023-60	1 in 1 CARTON	02/25/2019	
1		170 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-023-34	2 in 1 CARTON	02/25/2019	
2		170 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	02/25/2019	

Labeler - Colgate-Palmolive Company (001344381)

Establishment

Name	Address	ID/FEI	Business Operations
Colgate-Palmolive		785047999	MANUFACTURE(35000-023)