

**COLGATE SENSITIVE ENAMEL PROTECT- sodium fluoride and potassium nitrate paste, dentifrice**

**Mission Hills S.A de C.V**

**Reference Label Set Id: eb309cfc-d8df-4612-9c4e-622f0da1a579**

*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® Sensitive Enamel Protect Fluoride Toothpaste 4.0oz**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
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, glycerin, hydrated silica, PEG-12, sodium lauryl sulfate, flavor, cellulose gum, tetrasodium pyrophosphate, sodium saccharin, xanthan gum, titanium dioxide

**Questions or comments?**

Call toll-free **1-800-468-6502**

Dist. by:

**COLGATE-PALMOLIVE COMPANY**

New York, NY 10022

**PRINCIPAL DISPLAY PANEL - 113 g Tube Carton**

**Colgate®**

**Toothpaste for Sensitive Teeth and Cavity Protection**

**MAXIMUM STRENGTH\***

**Sensitive  
enamelprotect**

**Clinically Proven  
Sensitivity Relief**

NET WT 4.0 OZ (113 g)

- ▣ **Helps Protect Against Acid Wear**
- ▣ **Hardens Enamel**

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Toothpaste for Sensitive Teeth and Cavity Protection



**Clinically Proven**  
Sensitivity Relief

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Dist. by:  
**COLGATE-PALMOLIVE COMPANY**  
New York, NY 10022 Made in Mexico  
www.colgatesensitive.com

# Colgate®



**Clinically Proven**  
Sensitivity Relief

MAXIMUM STRENGTH\*

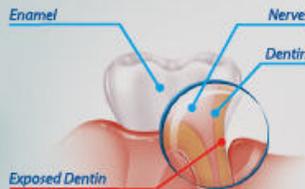
# Sensitive

enamelprotect

Helps protect against Acid Wear due to:



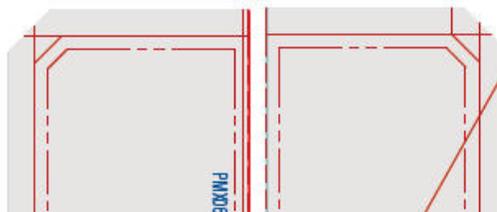
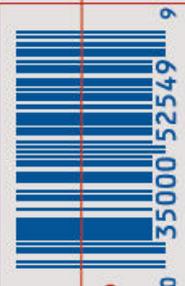
Remineralizes the enamel, hardening the tooth surface.

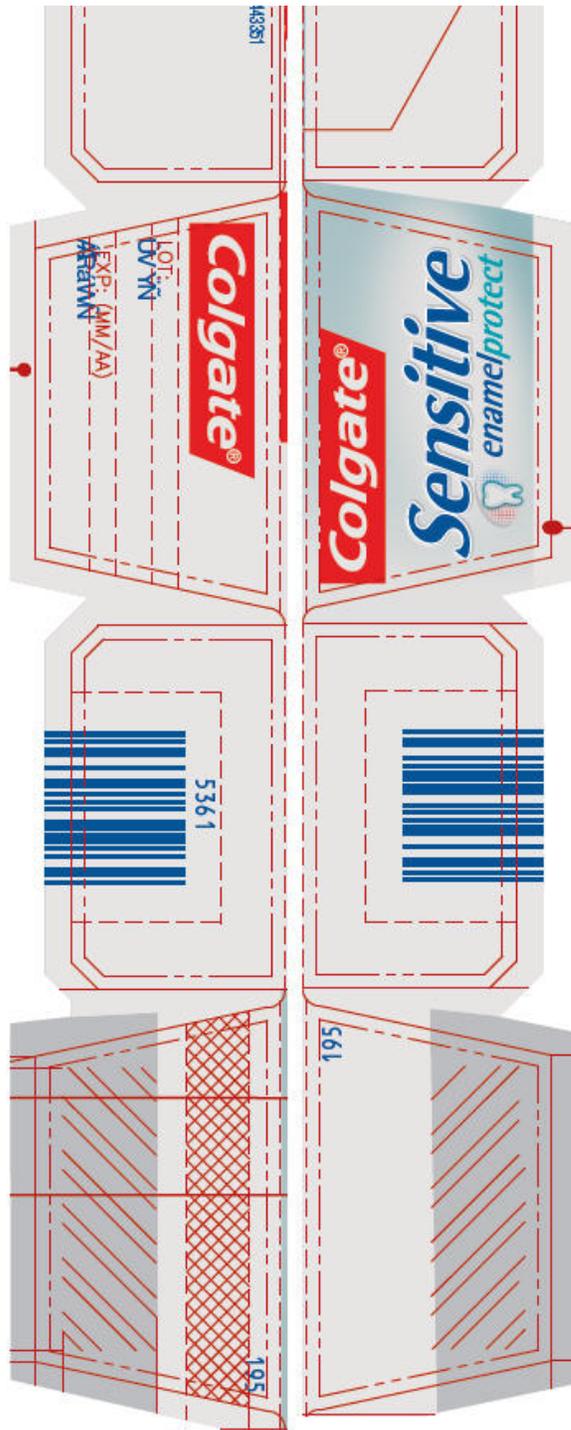


Brush with Colgate® Sensitive 2x a day

- ✓ Contains Potassium Nitrate, clinically proven to soothe the nerves in exposed dentin.
- ✓ Provides fast relief within two weeks.
- ✓ Builds increasing protection against sudden shocks of painful sensitivity.
- ✓ Provides long term relief with regular use.
- ✓ Contains Fluoride for cavity protection.
- ✓ Great tasting flavor.

\*Maximum strength FDA allowed antisensitivity active ingredient





## COLGATE SENSITIVE ENAMEL PROTECT

sodium fluoride and potassium nitrate paste, dentifrice

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65954-044
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 mg in 1 g
<b>POTASSIUM NITRATE</b> (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	50 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	363 mg in 1 g
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 600</b> (UNII: NL4J9F21N9)	
<b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	SPEARMINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65954-044-69	1 in 1 CARTON		
1		113 g in 1 TUBE		
2	NDC:65954-044-60	1 in 1 CARTON		
2		170 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/30/2010	

**Labeler** - Mission Hills S.A de C.V (812312122)