

CVS ENAMEL GUARD- fluoride paste, dentifrice

CVS Pharmacy

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.

Drug Facts

Active ingredients / Purpose

Potassium nitrate 5%.....Antihypersensitivity

Sodium fluoride 0.15% w/v fluoride ion.....Anticavity

Uses

- aids in reducing sensitivity
- aids in the prevention of dental cavities

When using this product do not use longer than 4 weeks unless recommended by a dentist or physician. **See your dentist if** the problem 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

Brush teeth thoroughly for at least one minute, preferably after each meal or at least twice a day (morning and evening) or as recommended by a dentist or physician. Make sure to brush all sensitive areas of the teeth. Do not swallow.

Apply at least a 1-inch strip of the product onto a soft bristle toothbrush. **Children under 12 years of age:** consult a dentist or a doctor.

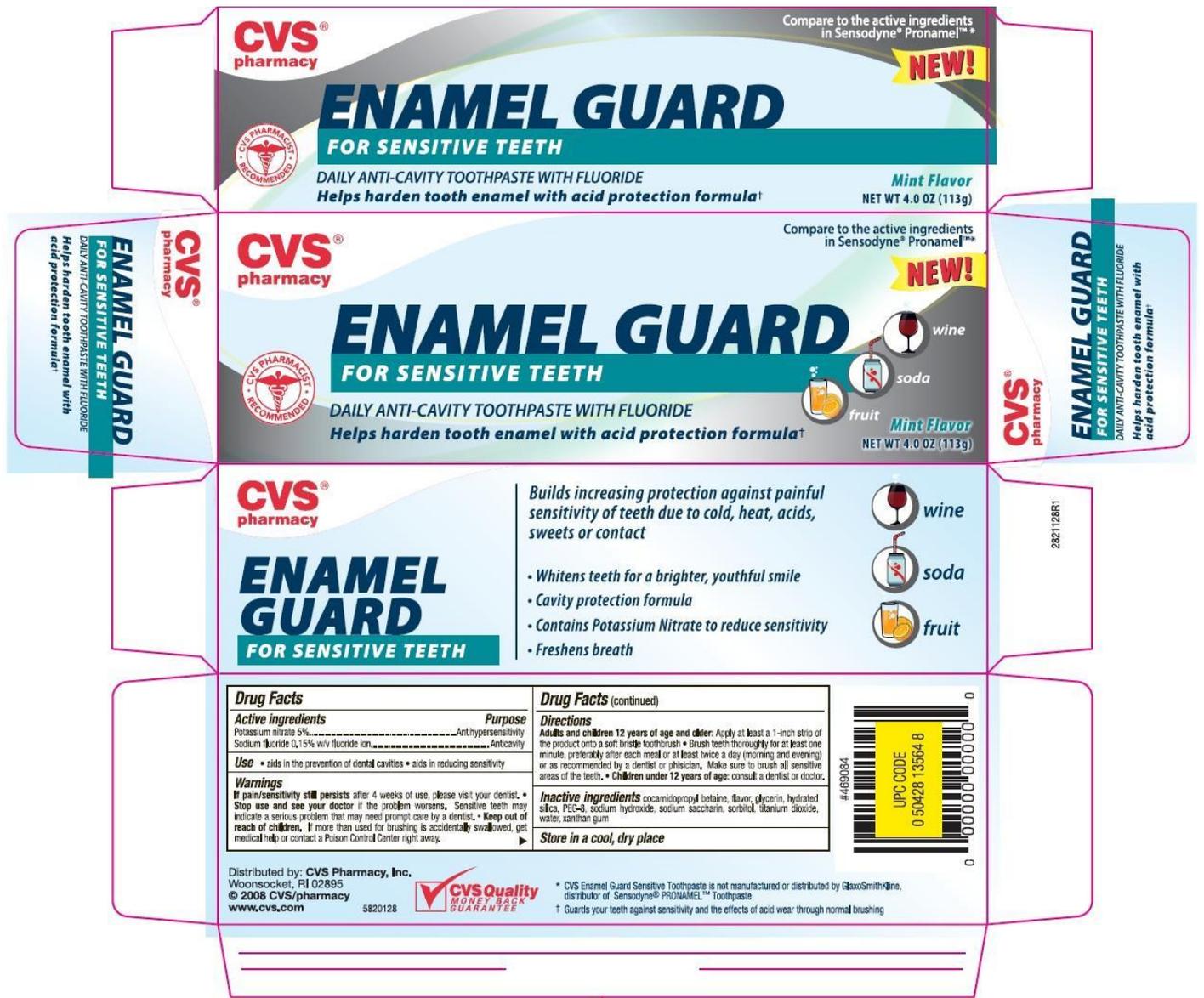
Other Information

Store in a cool dry place. Keep tube capped when not in use.

Inactive ingredients

cocamidopropyl betaine, flavor, glycerin, hydrated silica, PEG-8, sodium hydroxide, sodium methyl cocoyl taurate, sodium saccharin, sodium tripolyphosphate, sorbitol, titanium dioxide, water, xanthan gum

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Compare to the active ingredients
in Sensodyne® Pronamel™*

NEW!

ENAMEL GUARD

FOR SENSITIVE TEETH

DAILY ANTI-CAVITY TOOTHPASTE WITH FLUORIDE
Helps harden tooth enamel with acid protection formula†

Mint Flavor
NET WT 4.0 OZ (113g)



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ENAMEL GUARD

FOR SENSITIVE TEETH

Builds increasing protection against painful sensitivity of teeth due to cold, heat, acids, sweets or contact

- Whitens teeth for a brighter, youthful smile
- Cavity protection formula
- Contains Potassium Nitrate to reduce sensitivity
- Freshens breath



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Drug Facts

Active ingredients
Potassium nitrate 5%.....Antihypersensitivity
Sodium fluoride 0.15% w/v fluoride ion.....Anticavity

Use • aids in the prevention of dental cavities • aids in reducing sensitivity

Warnings
If pain/sensitivity still persists after 4 weeks of use, please visit your dentist. • Stop use and see your doctor if the problem 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.

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 one minute, preferably after each meal or at least 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 of age: consult a dentist or doctor.

Inactive ingredients cocamidopropyl betaine, flavor, glycerin, hydrated silica, PEG-8, sodium hydroxide, sodium saccharin, sorbitol, titanium dioxide, water, xanthan gum

Store in a cool, dry place



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* CVS Enamel Guard Sensitive Toothpaste is not manufactured or distributed by GlaxoSmithKline, distributor of Sensodyne® PRONAMEL™ Toothpaste
† Guards your teeth against sensitivity and the effects of acid wear through normal brushing



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182112&R1

CVS ENAMEL GUARD

fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-128
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.5 g in 1 g
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 1 g

Inactive Ingredients

Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	

Product Characteristics

Color	white (white to light tan)	Score	
Shape		Size	
Flavor	MINT (mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-128-89	1 in 1 CARTON	11/30/2012	
1	NDC:59779-128-82	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	01/20/2011	

Labeler - CVS Pharmacy (062312574)

Registrant - Lornamead (126440440)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		078584069	manufacture(59779-128) , pack(59779-128)