CVS PHARMACY ENAMEL GUARD- sodium fluoride and potassium nitrite 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

Uses

aids in the prevention of dental caviites aids in reducing sensitivity

If pain/sensitivity 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. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children. Children under 12 years of age: consult a dentist or doctor

Directions

Adults and children 12 years of age and older: apply at least a 1-inch strip of the product onto a soft bristle toothbruch. Brush teeth thorughly for at least one minute, preferably after each meal or at least twice a day (morning and evening) or as directed by a dentist or physician. Make sure to brush all sensitive areas of the teeth.

Other Information

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

Inactive ingredients

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

Adults and children 12 years of age and older: apply at least a 1-inch strip of the product onto a soft bristle toothbruch.

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Compare to the active ingredients in Sensodyne® ProNamel® Alpine Breeze**

ENAMEL GUARD

GENTLE WHITENING FOR SENSITIVE TEETH

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

Alpine Mint Flavor NET WT 4.0 OZ (113 g)

Drug Facts

Active ingredient Potassium nitrate 5% Sodium fluoride 0,15% w/v fluoride ion.

Purpose Antihypersensitivity Anticavity

Uses . builds increasing protection against painful sensitivity of the teeth to

protection formula[†]

cold, heat, acids, sweets or contact • aids in the prevention of dental cavities

Warnings When using this product do not use longer than 4 weeks unless recommended by a dentist or physician. See your 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,

*CVS/pharmacy® Enamel Protection Daily Anti-Cavity Toothpaste with Fluoride is not manufactured or distributed by GlaxoSmithKline, distributor of Sensodyne® ProNamel® Alpine Breeze™ toothpaste..

†Guards your teeth against sensitivity and the effects of acid wear through normal brushing.

Drug Facts (continued)

Directions

Adults and children 12 years of age and older: Apply st 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, • Do not swallow • Children under 12 years of age: consult a dentist or physician.

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

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CVS PHARMACY ENAMEL GUARD

fluoride paste, dentifrice

Product Information

HUMAN OTC DRUG LABEL Item Code (Source) NDC:59779-815 Product Type

Route of Administration DENTAL DEA Schedule

Active Ingredient/Active Moiety

821164R

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (FLUORIDE ION)	FLUORIDE ION	0.15 g in 100 g
POTASSIUM NITRITE (NITRITE ION)	POTASSIUM NITRITE	5.0 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
SORBITOL		
TITANIUM DIO XIDE		
GLYCERIN		
SACCHARIN SO DIUM		
WATER		
SO DIUM HYDRO XIDE		
XANTHAN GUM		
CO CAMIDO PRO PYL BETAINE		
POLYETHYLENE GLYCOL 400		
HYDRATED SILICA		

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:59779-815-49	1 in 1 CARTON		
1	NDC:59779-815-42	113 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/01/2012	

Labeler - CVS Pharmacy (062312574)

Registrant - Lornamead (126440440)

Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(59779-815), pack(59779-815)

Revised: 1/2013 CVS Pharmacy