

CVS PHARMACY 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.

5820164 CVS Sens Enamel Guard Mint

Active ingredients

Potassium Nitrate 5%.....Antihypersensitivity
Sodium Fluoride 0.15% w/v fluoride ion.....Anticavity

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 thoroughly 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

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-815
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.15 g in 100 g
POTASSIUM NITRITE (UNII: 794654G42L) (NITRITE ION - UNII:J39976L608)	POTASSIUM NITRITE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
XANTHAN GUM (UNII: TTV12P4NEE)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	

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	01/07/2013	
1	NDC:59779-815-42	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	10/01/2012	

Labeler - CVS Pharmacy (062312574)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(59779-815) , pack(59779-815)