

TOP CARE ENAMEL GUARD- fluoride paste, dentifrice
TOPCO Assoc. LLC

5820186 Topco Enamel Guard

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 saccharin, sorbitol, titanium dioxide, water, xanthan gum

TOP CARE ENAMEL GUARD			
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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-681
Route of Administration	DENTAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.15 g in 100 g
	POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 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: PDC6A3C00X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
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:36800-681-19	1 in 1 CARTON	11/20/2012	
1		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 Drug	M022	01/20/2011	

Labeler - TOPCO Assoc. LLC (006935977)**Registrant** - Lornamead (080046418)**Establishment**

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	pack(36800-681) , manufacture(36800-681)

Revised: 2/2024

TOPCO Assoc. LLC