

**TOPCO ASSOCIATES LLC MAXIMUM STRENGTH- fluoride paste, dentifrice**  
**Topco Associates LLC**

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**5820184 Topco Max Str Sens Mint**

**Active ingredients / Purpose**

Potassium nitrate 5%.....Antihypersensitivity

Sodium fluoride 0.24% (0.15% w/v fluoride ion).....Anticavity

**Uses**

aids in the prevention of dental cavities

**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.

**Directions**

**Adults and children 12 years of age and older:** Apply at least a 1-inch strip of 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.

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

**TOPCO ASSOCIATES LLC MAXIMUM STRENGTH**

fluoride paste, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-481
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.15 g in 100 g
<b>POTASSIUM NITRATE</b> (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)				
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)				
SORBITOL (UNII: 506T60A25R)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
GLYCERIN (UNII: PDC6A3C0OX)				
XANTHAN GUM (UNII: TTV12P4NEE)				
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
Product Characteristics				
Color	green		Score	
Shape			Size	
Flavor	MINT (mint)		Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-481-49	1 in 1 CARTON	11/15/2012	
1	NDC:36800-481-42	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 Drug		M022	01/20/2011	

**Labeler -** Topco Associates LLC (006935977)

**Registrant -** Lornamead (080046418)

Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(36800-481) , pack(36800-481)