

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

5820184 Topco Max Str Sens Mint (80-15206 upd)

Inactive ingredients

water, sorbitol, hydrated silica, glycerin, cocamidopropyl betaine, xanthan gum, flavor, titanium dioxide, sodium saccharin, sodium hydroxide, sucralose, yellow 10, blue 1

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 twice a day (morning and evening), and not more than 3 times a day, or as recommended by a dentist or doctor. Make sure to brush all sensitive areas of the teeth. Minimize swallowing. Spit out after brushing.
- **children under 12 years of age:** Consult a dentist or doctor.

Uses

- builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact
- aids in the prevention of dental cavities

When using this product, if irritation occurs discontinue use.

Stop use and ask a dentist if

- the problem persists or worsen
- Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.
- pain/sensitivity still persists after 4 weeks of use

Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Center right away.

Active ingredients / Purpose

Potassium nitrate 5%.....Antihypersensitivity

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

adults and children 12 years of age and older: 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.



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fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-364
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 NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	

HYDRATED SILICA (UNII: Y6O7T4G8P9)				
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
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:36800-364-10	1 in 1 CARTON	06/26/2025	
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	06/26/2025		

Labeler - Topco Associates LLC (006935977)

Registrant - Lornamead (080046418)

Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(36800-364) , pack(36800-364)