

CARE ONE MAXIMUM STRENGTH- fluoride paste, dentifrice
American Sales

5820111 Care One Max Str Sensitive Extra Whitening

Active ingredients

Potassium nitrate 5%

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

Purpose

Antihypersensitivity

Anticavity

Uses

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

Directions

Adults and children 12 years of age and older: Apply at 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.
- **Children under 12 years of age:** consult a dentist or physician.

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

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

DISTRIBUTED BY:

American Sales Company

4201 Walden Avenue

Lancaster, NY 14086

CARE ONE MAXIMUM STRENGTH

fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-582
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)	
SODIUM TRIPOLYPHOSPHATE (UNII: 5HK03SA80J)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C00X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT (mint)	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-582-19	1 in 1 CARTON	01/20/2013	
1	NDC:41520-582-12	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	01/20/2013	

Labeler - American Sales (809183973)

Registrant - Lornamead Inc. (080046418)

Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead Inc.		080046418	manufacture(41520-582)