# CARE ONE MAXIMUM STRENGTH- fluoride paste, dentifrice American Sales

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.

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#### **Drug Facts**

# 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

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 physican. 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.

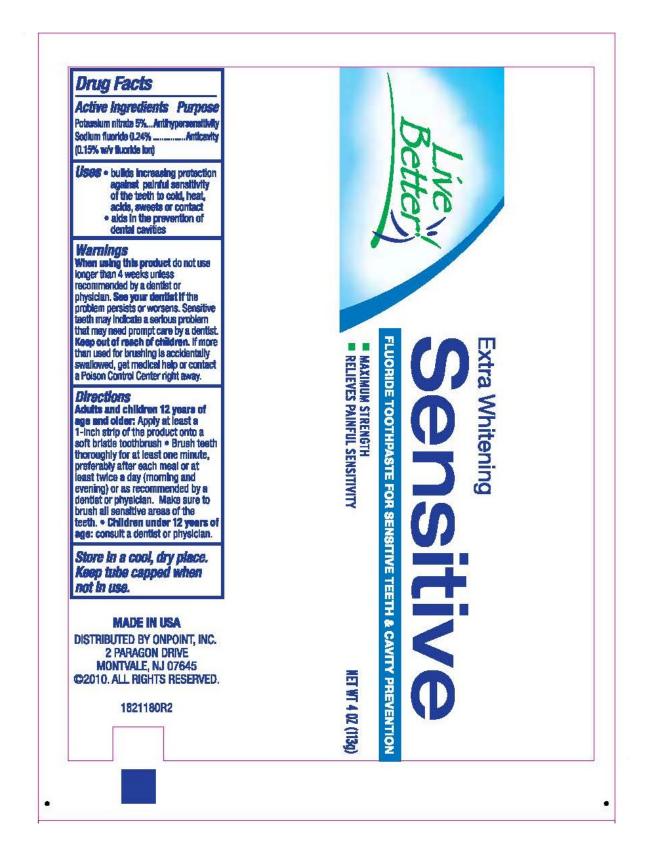
# Inactive ingredients

cocamidopropyl betaine, flavor, glycerin, hydrated silica, PEG-8, sodium hydroxide, sodium methyl cocoyl taurate, sodium saccharin, sodium tripolyphosphate, sorbitol, titanium dioxide, water, xanthan gum

mm1.jpg



mm2.jpg



Product Information	on				
Product Type			NDC:41520-111		
		nem coute (			
Route of Administrati	on DENTAL				
Active Ingredient/	Active Moiety				
Ingredient Name Basis of Strengtl					
SODIUM FLUORIDE (U	DE 0.24 g in 100 g				
<b>POTASSIUM NITRATE</b> (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844) NITRATE ION					
Inactive Ingredien	ts				
Ingredient Name					
WATER (UNII: 059QF0K	OOR)				
SACCHARIN SODIUM (	UNII: SB8ZUX40TY)				
SO DIUM TRIPO L YPHO	<b>SPHATE</b> (UNII: 5HK03SA80J)				
POLYETHYLENE GLYC	C <b>OL 400</b> (UNII: B697894SGQ)				
SORBITOL (UNII: 506T	60A25R)				
<b>FITANIUM DIO XIDE</b> (U	NII: 15FIX9V2JP)				
SO DIUM HYDRO XIDE (	UNII: 55X04QC32I)				
GLYCERIN (UNII: PDC6	A3C0OX)				
XANTHAN GUM (UNII: T	TV12P4NEE)				
HYDRATED SILICA (UN	NII: Y6O7T4G8P9)				
COCAMIDOPROPYL B	ETAINE (UNII: 50CF3011KX)				
SODIUM METHYL COC	OYL TAURATE (UNII: JVL980	CG53G)			
Product Character	istics				
Color		Score			
Shape	Score				
Flavor MINT (mint)			Imprint Code		
Contains	with (mill)	miprint Cot			
Contains					
Packaging					
# Item Code	Package Description	on Marketing Star	rt Date Marl	keting End Date	
NDC:41520-111-19	1 in 1 CARTON				
NDC:41520-111-12	113 g in 1 TUBE				
Marketing Info	rmation				
Marketing Category	Application Number or	Monograph Citation Ma	rketing Start Date	Marketing End Dat	
OTC monograph not fina	l part356	0.1/0/	0/2011		

# Registrant - Lornamead (126440440)

Establishment						
Name	Address	ID/FEI	Business Operations			
Lornamead		126440440	manufacture(41520-111) , pack(41520-111)			

Revised: 11/2012

American Sales