

**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 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

mm1.jpg



## Drug Facts

### Active Ingredients Purpose

Potassium nitrate 5%...Antihypersensitivity  
Sodium fluoride 0.24% .....Anticavity  
(0.15% w/v fluoride ion)

**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.

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

**MADE IN USA**

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MONTVALE, NJ 07645  
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1821180R2



Extra Whitening

# Sensitive

FLUORIDE TOOTHPASTE FOR SENSITIVE TEETH & CAVITY PREVENTION

■ MAXIMUM STRENGTH  
■ RELIEVES PAINFUL SENSITIVITY

NET WT 4 OZ (113g)

fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-111
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.24 g in 100 g
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	NITRATE ION	5.0 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
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: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (mint)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-111-19	1 in 1 CARTON		
1	NDC:41520-111-12	113 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/20/2011	

**Labeler** - American Sales (809183973)

**Registrant** - Lornamead (126440440)

**Establishment**

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

Revised: 11/2012

American Sales