

## **LORNAMEAD NATURAL WHITE- fluoride paste, dentifrice**

### **Lornamead**

*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 ingredient**

Potassium nitrate 5% ..... Antisensitivity

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

**When using this product** do not use longer than 4 weeks unless recommended by a dentist or physician. **Stop use and ask a dentist if** the sensitivity problem worsens. Sensitive teeth may indicate a serious problem that may need prompt care.

**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, twice a day (morning and evening) or as recommended by a dentist. Make sure to brush all sensitive areas of the teeth.

Do not swallow

Apply at least a 1-inch strip of the product onto a soft bristle toothbrush. **Children under 12 years of age:** ask a dentist.

#### **Other Information**

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

#### **Inactive ingredients**

Water, Hydrated Silica, Sorbitol, Glycerin, Cocamidopropyl Betaine, PEG-12, Titanium Dioxide, Cellulose Gum, Flavor, Sodium Benzoate, Sodium Saccharin, Red 40

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<b>Drug Facts</b>		<b>Drug Facts</b> (continued)	
<b>Active Ingredients</b> Potassium nitrate 5% Sodium fluoride 0.24% (0.15% w/v fluoride ion)	<b>Purpose</b> Antihypersensitivity Anticavity	<b>Directions</b> 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.	
<b>Uses</b> • builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact • aids in the prevention of dental cavities		<b>Inactive ingredients</b> water, hydrated silica, sorbitol, glycerin, cocamidopropyl betaine, PEG-12, titanium dioxide, cellulose gum, flavor, sodium benzoate, sodium saccharin, red 40	
<b>Warnings</b> 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.		<b>Store in a cool, dry place.</b> <b>Keep tube capped when not in use.</b>	

2821139R1



\*Compare to the active ingredients in Sensodyne®

# NATURAL WHITE Sensitive

**WHITENING TOOTHPASTE**  
Helps relieve pain from cold, heat, acids or sweets

**Extreme**

- WHITENS TEETH
- FIGHTS CAVITIES WITH FLUORIDE

NET WT. 4.5 OZ / 128 g

select brand Sensitive Extreme WHITENING TOOTHPASTE



\*Compare to the active ingredients in Sensodyne®

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Get the Smile You've Always Wanted!




Distributed by:  
SELECT BRAND® DISTRIBUTORS  
Pine Bluff, AR 71603 USA  
(870) 535-3635  
MADE IN USA

\*Select Brand Sensitive Whitening Toothpaste is not manufactured or distributed by GlaxoSmithKline, distributor of Sensodyne® Toothpaste

ITEM #1300284



UPC CODE  
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select brand Sensitive Extreme WHITENING TOOTHPASTE

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<p><b>Drug Facts</b></p> <p><b>Active ingredients</b></p> <p>Potassium nitrate 5% ..... Antihypersensitivity</p> <p>Sodium fluoride 0.24% (0.15% w/v fluoride ion) ..... Anticavity</p> <p><b>Uses</b> • builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact</p> <ul style="list-style-type: none"> <li>• aids in the prevention of dental cavities</li> </ul> <p><b>Warnings</b> 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.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b></p> <p>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. • Do not swallow • Children under 12 years of age: consult a dentist or physician.</p> <p><b>Store in a cool, dry place.</b></p> <p><b>Keep tube capped when not in use.</b></p>
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Comments? Questions? Call 1-877-777-2743 or Email customerservice@lornameadna.com

Distributed by:  Lornamead, Inc.; Tonawanda, NY 14150  
 MADE IN USA 1011470R2 / 3011470

fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62721-0470
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SODIUM TRIPOLYPHOSPHATE (UNII: 5HK03SA80J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Vanilla Mint)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62721-0470-9	1 in 1 CARTON		
1	NDC:62721-0470-2	128 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	12/01/2012	

**Labeler** - Lornamead (126440440)

**Registrant** - Lornamead (126440440)

**Establishment**

Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(62721-0470) , pack(62721-0470)

Revised: 1/2013

Lornamead