

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.

Natural White Extreme Sensitive Toothpaste

Drug Facts

Active ingredient

Potassium Nitrate 5% (w/w)

Sodium Fluoride 0.24% (w/w)

Purpose

Antihypersensitivity

Anticavity

Use

aids in the prevention of dental cavities

Warnings

If pain/sensitivity still persists after 4 weeks of use, please visit your dentist.

- **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.
- **Children under 12 years of age:** consult a dentist or doctor.

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

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

Manufactured by:

Lornamead, Inc.

Tonawanda, NY 14150

Made in USA

Comments? Questions?

Email us at: customerservice@lornamead.com

or call 1-877-777-2743

Natural White

Extreme Sensitive

WHITENING TOOTHPASTE

TARTAR CONTROL

REDUCES SENSITIVITY

FIGHTS CAVITIES

NET WT. 4.5 OZ / 128 g

<p>Drug Facts</p> <p>Active Ingredients Potassium Nitrate 5% (w/w) Antihypersensitivity Sodium Fluoride 0.24% (w/w) Anticavity</p> <p>Purpose Anticavity</p> <p>Uses Aids in the prevention of dental cavities</p> <p>Warnings 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.</p>	<p>Drug Facts (continued)</p> <p>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 doctor. Make sure to brush sensitive areas of the teeth. Children under 12 years of age: consult a dentist or doctor.</p> <p>Inactive Ingredients Water, Sorbitol, Hydrated Silica, Glycerin, Cocamidopropyl Betaine, Tetrapotassium Pyrophosphate, Flavor, PEG-12, Cellulose Gum, Titanium Dioxide, Sodium Benzoate, Sodium Saccharin, Red 40</p>
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LORNAMEAD NATURAL WHITE

fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62721-0471
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.24 g in 100 g
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	

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, UNSPECIFIED FORM (UNII: K679OBS311)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	MINT (Vanilla Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62721-0471-9	1 in 1 CARTON	12/01/2012	
1		128 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 not final	part356	12/01/2012	

Labeler - Lornamead (126440440)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead Inc.		078584069	manufacture(62721-0471)

Revised: 12/2018

Lornamead