

**MEIJER ENAMEL GUARD- potassium nitrate, sodium fluoride paste, dentifrice**

**Meijer Distribution Inc**

*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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**Meijer Enamel Guard Toothpaste Sensitive**

***Drug Facts***

***Active ingredients***

Potassium nitrate 5%

Sodium fluoride 0.15% w/v fluoride ion

***Purpose***

Antihypersensitivity

Anticavity

***Uses***

- aids in the prevention of dental cavities
- aids in reducing sensitivity

***Warnings***

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

**Stop use and ask a 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 a doctor

***Inactive ingredients*** □ water, hydrated silica, sorbitol, glycerin, PEG-8, cocamidopropyl betaine, flavor, titanium dioxide, xanthan gum, sodium saccharin, sodium hydroxide

***Store in a cool dry place***

DIST. BY MEIJER DISTRIBUTION, INC.

GRAND RAPIDS, MI 49544

www.meijer.com

MADE IN USA

**meijer™**

**Enamel Guard Toothpaste**

Daily Anti-cavity Fluoride Toothpaste for Sensitive Teeth

Helps Harden Enamel  
 Alpine Mint  
 NET WT 4.0 OZ (113 g)

**meijer** *Alpine Mint*  
**EnamelGuard Toothpaste**  
 Daily Anti-Cavity Fluoride Toothpaste for Sensitive Teeth  
**Helps harden enamel**  
 NET WT 4.0 OZ (113 g) Protects against effects of acid wear from wine, fruits & soda\*

**meijer** *Alpine Mint*  
**EnamelGuard Toothpaste**  
 Daily Anti-Cavity Fluoride Toothpaste for Sensitive Teeth  
**Helps harden enamel**  
 NET WT 4.0 OZ (113 g) Protects against effects of acid wear from wine, fruits & soda\*

**Meijer™ Enamel Guard Daily Anti-Cavity Fluoride Toothpaste** builds increasing protection against painful sensitivity of teeth due to cold, heat, acids, sweets or contact.

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 GRAND RAPIDS, MI 49544  
 www.meijer.com

**MADE IN USA**

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- Whitens teeth for a brighter, more youthful smile
- Cavity protection formula
- Contains potassium nitrate to reduce sensitivity
- Freshens breath

Drug Facts	Drug Facts (continued)
<b>Active ingredients</b> Potassium nitrate 5% Sodium fluoride 0.15% w/v fluoride ion	<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. Minimize swallowing. Spit out after brushing. • Children under 12 years of age: consult a dentist or doctor.
<b>Purpose</b> Antisensitivity Anticavity	<b>Other information</b> Store in a cool, dry place. Keep tube capped when not in use.
<b>Use</b> • aids in the prevention of dental cavities • aids in reducing sensitivity	<b>Inactive ingredients</b> water, hydrated silica, sorbitol, glycerin, PEG-8, cocamidopropyl betaine, flavor, titanium dioxide, xanthan gum, sodium saccharin, sodium hydroxide
<b>Warnings</b> 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.	<b>Questions or comments?</b> call 1-877-777-2743

\* This product is not manufactured or distributed by GlaxoSmithKline LLC, Safford-Miller (Ireland) Limited, or SmithKline Beecham Corporation, owners of the respective trademarks Sensodyne®, ProNamel® and Alpine Breeze™.

† Guards your teeth against sensitivity and the effects of acid wear through normal brushing.

MEIJER ENAMEL GUARD			
potassium nitrate, sodium fluoride paste, dentifrice			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-514
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
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	

## Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-514-09	1 in 1 CARTON	02/25/2019	
1		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 not final	part356	02/25/2019	

**Labeler** - Meijer Distribution Inc (006959555)

**Registrant** - Lornamead Inc. (078584069)

## Establishment

Name	Address	ID/FEI	Business Operations
Lornamead Inc.		078584069	manufacture(41250-514)