

**SOUND BODY SENSITIVE MAXIMUM STRENGTH- potassium nitrate, sodium fluoride paste, dentifrice**  
**Big Lots Stores, Inc.**

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**5820214 Sound Body Max Str Sensitive Toothpaste with Fluoride (8015201)**

**Drug Facts**

**Active ingredients**

Potassium nitrate 5%

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

**Purpose**

Antihypersensitivity

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

**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 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.

**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

**Comments/Questions: 1-877-777-2743**

MANUFACTURED BY:

Lornamead, Inc.

175 Cooper Avenue

Tonawanda, NY 14150

**MADE IN USA**

SOUND BODY

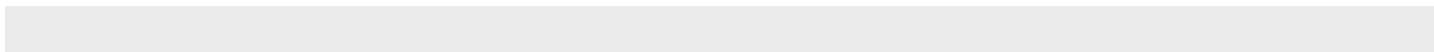
MAXIMUM STRENGTH

**SENSITIVE TOOTHPASTE WITH FLUORIDE**

- For sensitive teeth & cavity protection
- Relieves painful sensitivity

EXTRA WHITENING

**NET WT 4 OZ (113 g)**



# SOUND BODY SENSITIVE MAXIMUM STRENGTH

potassium nitrate, sodium fluoride paste, dentifrice

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50594-214
Route of Administration	DENTAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.15 g in 100 g
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
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: Y607T4G8P9)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50594-214-19	1 in 1 CARTON	03/05/2014	
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 Drug	M022	03/05/2014	

**Labeler** - Big Lots Stores, Inc. (017885351)

**Registrant** - Lornamead (078584069)

## Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(50594-214)

