SIGNATURE CARE SENSITIVE MAXIMUM STRENGTH- potassium nitrate, sodium fluoride paste, dentifrice Safeway

5820289, 5820040 Signature Care Maximum Strength Sensitive

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 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), and not more than 3 times a day, or as recommended by a dentist or physican. 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 physician.

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

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Signature Care™

MAXIMUM STRENGTH

SENSITIVE TOOTHPASTE WITH FLUORIDE

FOR SENSITIVE TEETH & CAVITY PROTECTION

RELIEVES PAINFUL SENSITIVITY

Extra Whitening

NET WT 4 OZ (113 g)

SIGNATURE CARE SENSITIVE MAXIMUM STRENGTH

potassium nitrate, sodium fluoride paste, dentifrice

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:21130-351

Route of Administration DENTAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	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, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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: 50CF3011KX)	

Product Characteristics

SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

99				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-351-19	1 in 1 CARTON	03/02/2019	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:21130-351-20	2 in 1 PACKAGE	03/02/2019	
2		1 in 1 CARTON		
2		113 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	03/02/2019	

Labeler - Safeway (009137209)

Registrant - Lornamead Inc. (080046418)

Establishment				
Name	Address	ID/FEI	Business Operations	
Lornamead Inc.		080046418	manufacture(21130-351)	

Revised: 2/2024 Safeway