

SENSITIVE EXTRA WHITENING- sodium fluoride paste, dentifrice
Publix Super Market

5820075 Publix Sensitive Extra Whitening (8015201)

Potassium nitrate 5%

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

Antihypersensitivity

Anticavity

builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact * acids in the prevention of dental cavities

When using this product, if irritation occurs discontinue.

Stop use and ask a dentist if * the problem persists or worsen. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. * pain/sensitivity still persists after 4 weeks of use.

Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Center right away.

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

water, sorbitol, hydrated silica, glycerin, pentasodium triphosphate, PEG-8, flavor, titanium dioxide, sodium methyl cocoyl taurate, cocamidopropyl betaine, xanthan gum, sodium hydroxide, sodium saccharin



SENSITIVE EXTRA WHITENING

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-413
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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
SORBITOL (UNII: 506T60A25R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
WATER (UNII: 059QF0KO0R)	

GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ)	

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:56062-413-33	1 in 1 CARTON	07/18/2024	
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	07/18/2024	

Labeler - Publix Super Market (006922009)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(56062-413) , pack(56062-413)