MEIJER MAXIMUM STRENGTH- fluoride paste, dentifrice Meijer

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.

Drug Facts

Active ingredients / Purpose

Potassium nitrate 5%......Antihypersensitivity
Sodium fluoride 0.24% (0.15% w/v fluoride ion).....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

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

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 physican. Make sure to brush all sensitive areas of the teeth.

Apply at least a 1-inch strip of the product onto a soft bristle toothbrush. **Children under 12 years of age:** consult a dentist or a doctor.

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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MEIJER MAXIMUM STRENGTH

fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-160
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	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		
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: Y6O7T4G8P9)			
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)			
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT (mint)	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41250-160- 09	1 in 1 CARTON	01/11/2023		
1	NDC:41250-160- 02	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	01/20/2011	

Labeler - Meijer (006959555)

Registrant - Lornamead (080046418)

Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(41250-160), pack(41250-160)

Revised: 1/2023 Meijer