

HEMP WITH FLOURIDE, SPEARMINT- sodium monofluorophosphate paste, dentifrice Lornamead

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.

8015030 Hemp with Fluoride, Spearmint

Sodium monofluorophosphate 0.76% (0.13% w/v fluoride ion) . . . Anticavity aids in the prevention of dental cavities

Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 2 years of age and older: brush teeth thoroughly, preferably after each meal or at least twice per day, or as directed by a dentist or doctor. * instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). * supervise children as necessary until capable of using without supervision. * children under 2 years of age: Consult a dentist or doctor.

Tamper evident, use only if box seal is intact. Keep tube capped when not in use. When using this product, if irritation occurs, discontinue use. Keep out of reach of children.

glycerin, water, calcium carbonate, hydrated silica, xylitol, sodium bicarbonate, carrageenan, cannabis sativa (hemp) seed oil, sodium sauroyl sarcosinate, natural flavor, zinc citrate, benzyl alcohol



HEMP WITH FLOURIDE, SPEARMINT

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62721-0030
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.76 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0KO0R)	
ZINC CITRATE (UNII: K72I3DEX9B)	
GLYCERIN (UNII: PDC6A3C0OX)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
SODIUM LAUROYL SARCO SINATE (UNII: 632GS99618)	
XYLITOL (UNII: VCQ006KQ1E)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Product Characteristics

Color	white (Off white)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62721-0030-9	156 g in 1 TUBE; Type 0: Not a Combination Product	06/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/19/2020	

Labeler - Lornamead (126440440)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(62721-0030)

Revised: 6/2020

Lornamead