

GRIN- sodium monofluorophosphate paste
GRIN NATURAL PRODUCTS LIMITED

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.

Active Ingredient

Sodium Monofluorophosphate 0.76% (1000ppm)

Purpose

Anticavity

Use

Aids in the prevention of dental cavities.

Keep out of reach of children under 6 years of age.

Warnings

If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center immediately. Do not use if you have an allergy to bees or bee products.

Directions

For best results brush at least twice daily after meals and use in conjunction with Grin dental floss. Children 6 years and under should use a smear of toothpaste and have adult supervision until good habits are established. Do not swallow, spit out excess toothpaste.

Inactive ingredients

Calcium Carbonate, Glycerine (Palm-free from Rapeseed), Aqua (Water), Xylitol, Lauryl Glucoside (Palm-free from Coconut), Sodium Bicarbonate, Chondrus crispus (Carrageenan) Gum, Foeniculum vulgare dulce (Fennel) Extract, Spearmint Flavour, Clove Flavour, Menthol, Xanthan Gum, Peppermint Oil, Organic NZ Sea Salt, Propolis cera (Propolis) Extract

Product Label



GRIN		
sodium monofluorophosphate paste		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)
Route of Administration	TOPICAL	NDC:78420-002
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUORO PHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.76 g in 100 g
Inactive Ingredients		
Ingredient Name	Strength	
CALCIUM CARBONATE (UNII: H0G9379FGK)		
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0K00R)		
XYLITOL (UNII: VCQ006KQ1E)		
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)		

CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)	
FOENICULUM VULGARE FRUIT (UNII: J5W36Y5WG8)	
SPEARMINT (UNII: J7I2T6IV1N)	
CLOVE (UNII: K48IKT5321)	
MENTHOL (UNII: L7T10EIP3A)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SEA SALT (UNII: 87GE52P74G)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78420-002-01	100 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/01/2020	

Labeler - GRIN NATURAL PRODUCTS LIMITED (594904384)