

GRIN KIDS- 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.

Directions

For best results brush at least twice daily after meals. Children 6 years and under should use a smear of toothpaste and have adult supervision.

Do not swallow, spit out excess toothpaste.

Inactive ingredients

Aloe Barbadensis (Aloe Vera) Leaf Extract Organic, Aqua (Water), Calcium Carbonate, Calendula Officinalis (Calendula) Oil Organic, Chondrus Crispus (Carrageenan) Gum, Foeniculum Vulgare Dulce (Fennel) Extract, Glycerine, Lauryl Glucoside, Menthol, Natural Strawberry Flavour, Organic NZ Sea Salt, Xanthan Gum, Xylitol.

Product Label



GRIN KIDS

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78420-001
Route of Administration	TOPICAL		

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
CALCIUM CARBONATE (UNII: H0G9379FGK)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
XYLITOL (UNII: VCQ006KQ1E)	

LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CALENDULA OFFICINALIS SEED OIL (UNII: 9JS8DS42SV)	
CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)	
FOENICULUM VULGARE FRUIT (UNII: J5W36Y5WG8)	
SEA SALT (UNII: 87GE52P74G)	
MENTHOL (UNII: L7T10EIP3A)	
XANTHAN GUM (UNII: TTV12P4NEE)	
STRAWBERRY (UNII: 4J2TY8Y81V)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78420-001-01	70 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)

Revised: 6/2020

GRIN NATURAL PRODUCTS LIMITED