

VITA FRESH - sodium monofluorophosphate paste, dentifrice
Cellinbio Co Ltd

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.

Vita Fresh Toothpaste

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.75%

Purpose

Anticaries

Keep out of Reach of Children

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 immediately.

Indication & Usage

Directions

Do not swallow

Supervise children as necessary until capable of using without supervision

Adults, Children 6 years of age, older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician.

Children under 6 years: Use only a pea sized amount and supervise child's brushing and rinsing(to minimize swallowing).

Children under 2 years: ask a dentist or doctor.

Warnings

Warnings

Stop use and ask a dentist if problems persists or worsens. Sensitive teeth may indicate a serious problem that may require prompt care by a dentist.

Dosage & Administration

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Inactive Ingredient

Silica, Tocopheryl Acetate, Aluminum chlorohydrate, Sorbitol, Polyethylene Glycol 1500, Hydrated silica, Cellulose Gum, Xylitol, Sodium Saccharin, Sodium Lauryl Sulfate, Camellia Sinensis Leaf Extract, Menthol, Mentha Viridis(Spearmint) Leaf Oil, Beta-carotene, CI 19140, CI 77480, Water

Vita Fresh Toothpaste

NRC Vita Fresh Toothpaste

Net WT. 5.29 OZ(150g)



VITA FRESH

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 173-1003
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM MONOFLUOROPHOSPHATE	1.125 g in 150 g

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINUM CHLOROHYDRATE (UNII: HPN8MZW13M)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
XYLITOL (UNII: VCQ006KQ1E)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
SPEARMINT OIL (UNII: C3M81465G5)	
BETA CAROTENE (UNII: 01YAE03M7J)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GOLD (UNII: 79Y1949PYO)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	yellow (green and black)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76173-1003-2	1 in 1 BOX		
1	NDC:76173-1003-1	150 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/27/2011	

Labeler - Cellinbio Co Ltd (557803737)

Registrant - Cellinbio Co Ltd (557803737)

Establishment

Name	Address	ID/FEI	Business Operations
Cellinbio Co Ltd		557803737	relabel

Establishment

Name	Address	ID/FEI	Business Operations
KOLMAR KOREA CO LTD		687846360	manufacture