

DENTAL CLINIC 2080 VITA CARE- sodium monofluorophosphate paste
Aekyung Industrial 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.

 If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away

Keep out of reach of children under 6 years of age

Sodium monofluorophosphate 0.75% (0.13% w/v Fluoride ion)

Sodium carboxymethylcellulose, Sodium lauryl sulfate, Sodium saccharin, Sorbitol, Titanium dioxide, Tocopheryl acetate, water, Ascorbic acid, Hydrated Silica, Menthol, PEG-32, Sodium metabisulfite, Coenzyme Q10, Flavor, Retinyl palmitate, D&C Yellow#10

Purpose Anticavity

Adults and children 2 years of age and older

Brush teeth thoroughly, preferably after each meal or at least twice a 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

Aids in the prevention of dental cavities



Drug Facts		Drug Facts (Continued)	
Active ingredient Sodium monofluorophosphate (0.75% (0.13% w/v Fluoride ion))	Purpose Anticavity	Directions	Brush teeth thoroughly, preferably after each meal or at least twice a 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.
Use Aids in the prevention of dental cavities.		Adults and children 2 years of age and older	Consult a dentist or doctor.
Warnings 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.		Children under 2 years of age	
Inactive ingredients Ascorbic acid, Coenzyme Q10, D&C Red#35, D&C Yellow#10, Flavor, Hydrated silica, Menthol, PEG-32, Retinyl palmitate, Sodium carboxymethylcellulose, Sodium lauryl sulfate, Sodium metabisulfite, Sodium saccharin, Sorbitol, Titanium dioxide, Tocopheryl acetate, Water			

AEKYUNG
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DENTAL CLINIC 2080 VITA CARE

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67225-0004
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.156 g in 120 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	72 g in 120 g
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	2.64 g in 120 g
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	0.48 g in 120 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	0.3 g in 120 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.12 g in 120 g
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.3 g in 120 g
HYDRATED SILICA (UNII: Y6O7T4G8P9)	22.92 g in 120 g
WATER (UNII: 059QF0K00R)	12.81 g in 120 g
MENTHOL (UNII: L7T10EIP3A)	0.3 g in 120 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67225-0004-1	1 in 1 PACKAGE	04/01/2015	
1		120 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 final	part355	04/01/2015	

Labeler - Aekyung Industrial Co., Ltd. (687995647)

Establishment

Name	Address	ID/FEI	Business Operations
Aekyung Ind. Co., Ltd._Chungyang Factory		690511126	manufacture(67225-0004)

