

DENTAL CLINIC 2080 CAVITY PROTECTION- sodium monofluorophosphate paste
Aekyung Ind. 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

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

AEKYUNG
Dental Clinic
Fluoride Anticavity Toothpaste

2080

Tooth-paste

Keep the 20 healthy teeth till 80 years old

AEKYUNG 4.2oz (120g)

• Cavity Protection • Whitening • Breath Freshening

Cavity Protection
Vitamin E
Double mint

Dental Clinic
2080
Cavity Protection
Double mint

Drug Facts		Drug Facts (Continued)	
Active ingredient	Purpose	Directions	
Sodium monofluorophosphate 0.75% (0.13% w/v Fluoride Ion)	Anticavity	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	
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	Consult a dentist or doctor.
Inactive ingredients FD&C Blue #1, Flavor, Hydrated silica, PEG-32, Sodium carboxymethylcellulose, Sodium lauryl sulfate, Sodium saccharin, Sorbitol, Titanium dioxide, Tocopheryl acetate, Water			

DENTAL CLINIC 2080 CAVITY PROTECTION

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67225-0001
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)	69.6 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)	0.156 g in 120 g

ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			0.3 g in 120 g	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67225-0001-1	120 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part355		12/01/2012	

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

Establishment			
Name	Address	ID/FEI	Business Operations
Aekyung Ind. Co., Ltd.		687995647	manufacture(67225-0001)