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 ad 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



DENTAL CLINIC 2080 CAVITY PROTECTION

sodium monofluorophosphate paste

Product Information					
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:67225-0001		
Route of Administration	DENTAL	DEA Sche dule			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM MONOFLUOROPHOSPHATE (FLUORIDE ION)	FLUORIDE ION	0.156 g in 120 g		

Inactive Ingredients				
Strength				
69.6 g in 120 g				
2.64 g in 120 g				
0.48 g in 120 g				
0.3 g in 120 g				
0.156 g in 120 g				
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 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)			

Revised: 12/2012 Aekyung Ind. Co., Ltd.