BRUSHBUDDIES BARBIE ANTICAVITY FLUORIDETOOTH- sodium monofluorophosphate paste, dentifrice

Foshan Nanhai Jiachun Biology Engineering 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.

Active Ingredient

Sodium Monofluorophosphate 0.76%

Purpose:

Anticavity Toothpaste

Uses:

Help protect teeth and roots against cavities

Warnings:

If morethan used for brushing is accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately

Keep out of reach of children

Directions:

- Adults and children 2 years and older:
- Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist.
- Do not swallow
- To minimize swallowing use a pea-sized amount in children under 6 years of age,
- Supervise children's brushing untill good habits are established.

Children under 2 years of age:

• Ask a dentist

Inactive Ingredients:

Sorbitor, Water, Silica, Sodium Lauryl Sulfate, Xylitol, Flavor, Sodium Carboxymethylcellulose, Sodium Benzoate, Xanthan Gum, Saccharin Sodium, Rose Red 1







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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71106-003	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	0.1 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		
XYLITOL (UNII: VCQ006KQ1E)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
XANTHAN GUM (UNII: TTV12P4NEE)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:71106-003-01	119 g in 1 TUBE; Type 0: Not a Combination Product	08/02/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	08/02/2018		

Labeler - Foshan Nanhai Jiachun Biology Engineering Co., Ltd. (527935253)

Establishment				
Name	Address	ID/FEI	Business Operations	
Foshan Nanhai JiaChun Biology Engineering Co., Ltd		527935253	manufacture(71106-003)	

Revised: 8/2018 Foshan Nanhai Jiachun Biology Engineering Co., Ltd.