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 more than 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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sodium monofluorophosphate paste, dentifrice

Product Information	on							
Product Type		HUMAN OTC DRUG	Item Co	ode (Source) NDC			DC:71106-003	
Route of Administrati	on	ORAL						
Active Ingredient/	Active Moie	ty						
Ingredient Name Basis o Strengt							Strengt	
SO DIUM MONOFLUOROPHO SPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)						DE ION	0.1 g in 100 g	
							III 100 g	
Inactive Ingredien	ts							
0		Ingredient Name					Strength	
WATER (UNII: 059QF0K	(00R)						-	
SORBITOL (UNII: 506T	60A25R)							
XYLITOL (UNII: VCQ00	6KQ1E)							
CARBO XYMETHYL CEI	LLULOSE SOD	IUM (UNII: K679OBS311)						
SODIUM BENZOATE (U	JNII: OJ245FE5E	U)						
XANTHAN GUM (UNII: 7	TV12P4NEE)							
SACCHARIN SODIUM (UNII: SB8ZUX4()TY)						
Packaging								
# Item Code	Р	ackage Description		Marketing Star	t Date	Marketi	ng End Dat	
NDC:71106-003-01	19 g in 1 TUBE;	Type 0: Not a Combination	Product 0	8/02/2018				
Marketing Info	rmation							
Marketing Category	Application	Number or Monograph	n Citation	Marketing Sta	rt Date	Marketi	ing End Dat	
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.