

BRUSHBUDDIES SHOPKINS ANTICAVITY TOOTH- sodium monofluorophosphate paste, dentifrice

Ashtel Studio Inc

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 0.5%

Purpose:

Anticavity

Uses:

Help protect teeth and roots against cavities

Warnings:

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

Keep out of reach of children under 6 years of age

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 until good habits are established.

Children under 2 years of age:

- Ask a dentist

Inactive Ingredients:

Sorbitol, Water, Silica, Sodium N-Lauroylsarcosinate, Xylitol, Flavor, Sodium Carboxymethylcellulose, Sodium Benzoate, Xanthan Gum, Sodium Pyrophosphate, Saccharin Sodium, Rose Red 1



BRUSHBUDDIES SHOPKINS ANTICAVITY TOOTH

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70 108-501
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.066 g in 100 g	
Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0K00R)			
SORBITOL (UNII: 506T60A25R)			

XYLITOL (UNII: VCQ006KQ1E)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70108-501-01	119 g in 1 TUBE; Type 0: Not a Combination Product	11/29/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/28/2016	

Labeler - Ashtel Studio Inc (148689180)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Nanhai JiaChun Biology Engineering Co., Ltd		527935253	manufacture(70108-501)

Revised: 11/2016

Ashtel Studio Inc