

**BRUSHBUDDIES THOMAS FRIENDS ANTICAVITY FLURORIDE TOOTH- 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 you 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 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, Saccharin Sodium, Rose Red 1

Brush Buddies®

**THOMAS
& FRIENDS**

**BUBBLE
GUM
GOMME À
BULLES**

NO 1



**ANTICAVITY FLUORIDE TOOTHPASTE
DENTIFRICE ANTICARIE AU FLUORURE**
4.2 oz (119 g)

make brushing fun!®

Brush Buddies®

Drug Facts

Active Ingredients

Sodium Monofluorophosphate-0.76%

Purpose

Anticavity Toothpaste

Uses

Helps protect teeth against cavities.

Warning KEEP OUT OF REACH OF CHILDREN.

If more than used for brushing is accidentally swallowed, seek professional assistance or contact a Poison Control Center immediately.

Directions

Adults and children 6 years of age and older:

- Brush teeth thoroughly after meals or at least twice a day. Use 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 brushing habit are established.
- Children under 2 years of age: Ask a dentist.

Inactive Ingredients

Sorbitol, Water, Silica, Sodium Lauryl Sulfate, Xylitol, Flavor, CMC Sodium Carboxymethyl Cellulose, Sodium Benzoate, Xanthan Gum, Saccharin Sodium, Rose Red.

Other Information

Store at room temperature.

Brush Buddies®

QUESTIONS OR COMMENTS?
1-877-274-8358 (U.S.A.)
1-909-434-0911 (INTERNATIONAL)

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Item # 00709-24



rendez le brossage amusant !

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BRUSHBUDDIES THOMAS FRIENDS ANTICAVITY FLUORIDE TOOTH

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71106-004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71106-004-01	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(71106-004)

Revised: 8/2018

Foshan Nanhai JiaChun Biology Engineering Co., Ltd