

SHOPKINS BUBBLE GUM MOUTH WASH- sodium fluoride liquid
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.

Anticavity

Keep out of reach of children. In case of accidental digestion seek professional assistance or contact a poison control center immediately.

□Active Ingredient Purpose

Sodium Fluoride 0.5% (0.23% w/v fluoride ion) Anticavity

Helps protect teeth and roots against cavities

keep out of reach of children.

If you accidentally swallow seek medical help or contact a poison control center immediately

Water, Glycerine, PEG-40 Hydrogenated Castor Oil, Propylene Glycol, Xylitol, Benzyl Alcohol, Flavor, Sodium Benzoate, Sodium Saccharin, Zinc Gluconate, FD&C Red 40, D&C Red 33

Adults and children 6 years and older:

Use daily after your normal brushing. Rinse toothpaste from your mouth prior to use.

Rinse or gargle for 30 seconds with 15ml (3 teaspoonful) and then spit it out.

Do not swallow the mouth wash

Route of Administration	DENTAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.05 mg in 100 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)			
	CITRAL PROPYLENE GLYCOL ACETAL (UNII: 9W7YHX7EX6)			
	ZINC GLUCONATE (UNII: U6WSN5SQ1Z)			
	SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE (UNII: B70850QPHR)			
	WATER (UNII: 059QF0KO0R)			
	.ALPHA-(.ALPHA.-AMINOPROPYL)BENZYL ALCOHOL HYDROCHLORIDE, ERYTHRO-(+/-)- (UNII: 3IIJ9C722I)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	XYLITOL (UNII: VCQ006KQ1E)			
	SODIUM BENZOATE (UNII: OJ245FE5EU)			
	SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
Product Characteristics				
Color	red (FD & C Red 33) , red (FD & C Red 40)	Score		
Shape		Size		
Flavor	BUBBLE GUM	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71106-001-01	479 g in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	01/11/2017		

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(71106-001)