

HOUSE LIVING- sodium monofluorophosphate paste
Guangzhou Beauty Cosmetic 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 ingredients

SODIUM MONOFLUOROPHOSPHATE 0.76%

Purpose

anticavity

Uses

Regular brushing with fluoride toothpaste helps protect teeth and roots against cavities.

Warnings

Keep out of the reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children.

Directions

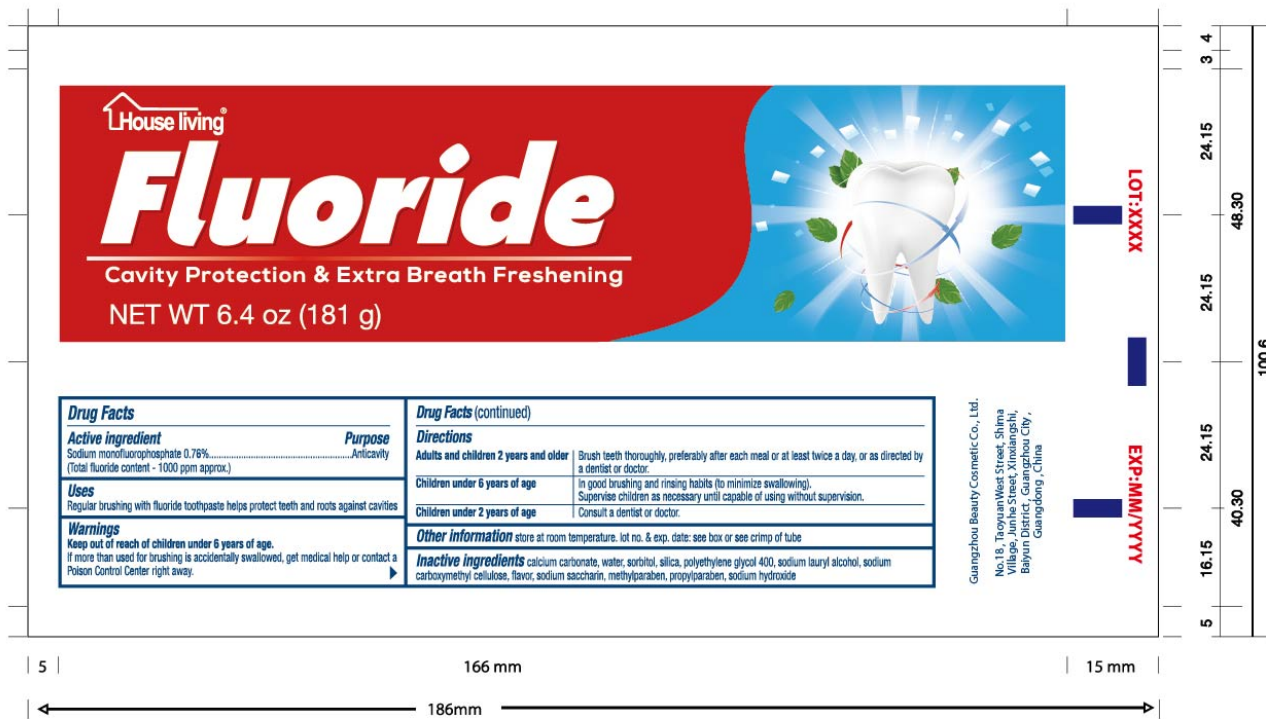
Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or a doctor.

Children under 6 years of age, in good brushing and rinsing habits (to minimize swallowing), supervise children as necessary until capable of using without supervision.

Children under 2 years of age: consult a dentist or doctor.

INACTIVE INGREDIENT

Water, Silica, Calcium Carbonate, Sodium Lauryl Alcohol, Sorbitol, Polyethylene Glycol 400, Sodium Carboxymethylcellulose, Sodium Saccharin, Sodium Hydroxide, Methyl Paraben, Propylparaben, Flavor



HOUSE LIVING

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71704-001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.76 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SORBITOL (UNII: 506T60A25R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71704-001-01	24 in 1 CARTON	09/13/2017	
1		128 g in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/13/2017	

Labeler - Guangzhou Beauty Cosmetic Co., Ltd (528735414)

Registrant - Guangzhou Beauty Cosmetic Co., Ltd (528735414)

Establishment			
Name	Address	ID/FEI	Business Operations
Guangzhou Beauty Cosmetic Co., Ltd		528735414	manufacture(71704-001)

Revised: 9/2017

Guangzhou Beauty Cosmetic Co., Ltd