

**HOUSE LIVING- sodium fluoride,potassium nitrate 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.*

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**Active Ingredient**

SODIUM FLUORIDE 0.15%

Potassium Nitrate 5%

**Purpose**

Antihypersensitivity

Anticavity

**Use**

builds increasing protection against painful sensitivity of the teeth due to cold,heat,acids,sweets or contact

aids in the prevention of dental cavities

**Warning**

Stop use and ask a dentist if

the problem persists or worsens,sensitive teeth may indicate a serious problem that may prompt care by a dentist

pain/sensitivity still persists after 4 weeks of use.

**Directions**

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

instruct children 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 Ingredients**

Water,Silica (Thickening 10 & Friction 4)

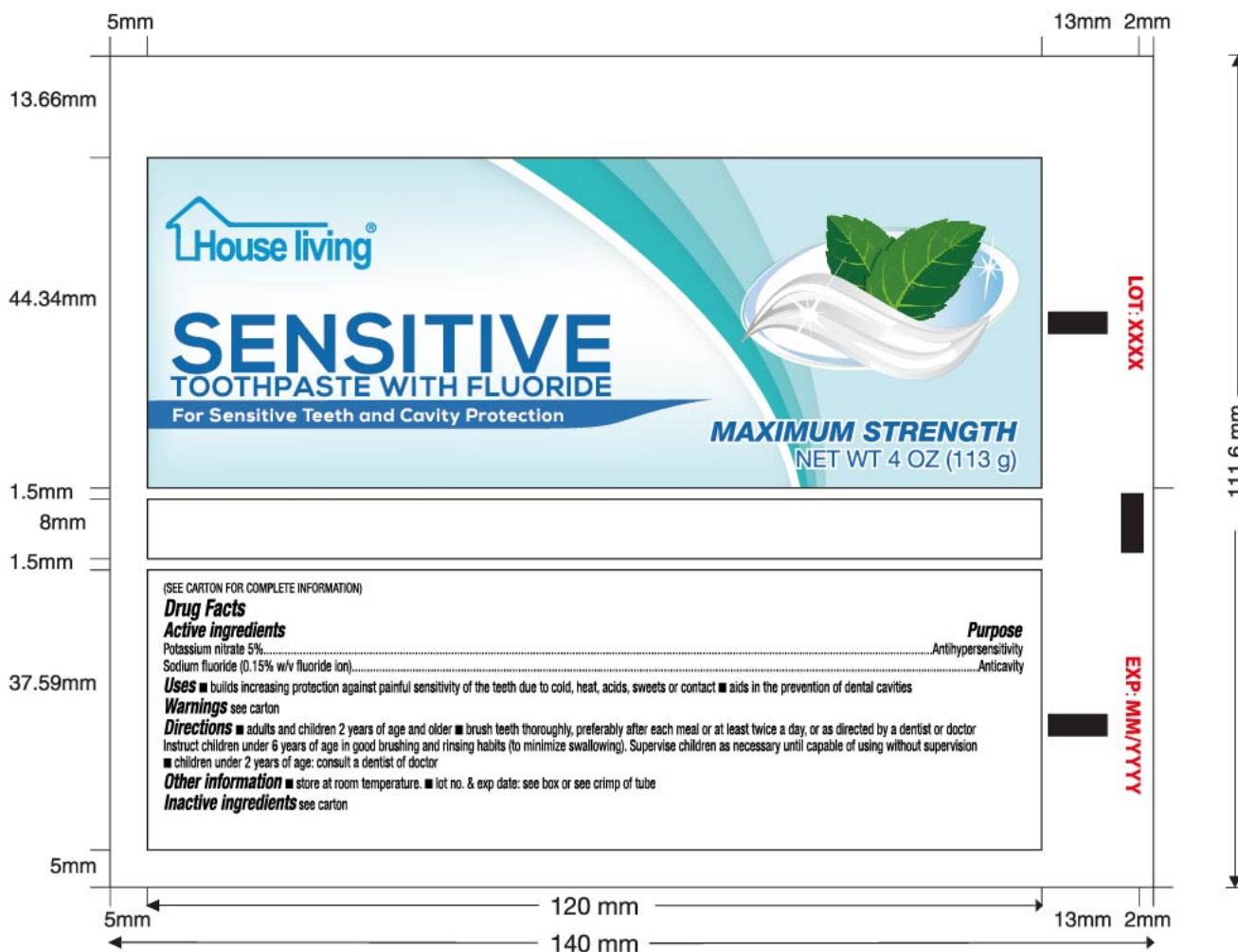
,Sodium Lauryl Alcohol,Sorbitol,Polyethylene Glycol 300,Sodium

Carboxymethylcellulose,Flavor,Sodium Saccharin,Titanium Dioxide,Sodium Pyrophosphate,PEG/PPG 116/66 copolymer

Sodium Hydroxide,Acid Yellow 23,Acid Blue 1

Keep out of 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.



Size : 35 dia x 140 mm

## HOUSE LIVING

sodium fluoride,potassium nitrate paste

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71704-002
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.15 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
PEG/PPG-116/66 COPOLYMER (UNII: JP0CK963E0)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM PYROPHOSPHATE DECAHYDRATE (UNII: IY3DKB96QW)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71704-002-01	24 in 1 CARTON	07/10/2016	
1		113 g in 1 TUBE; 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	07/10/2016	

**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(71704-002)

Revised: 9/2017

Guangzhou Beauty Cosmetic Co., Ltd