ADVANCED WHITENING ANTI CAVITY FLUORIDE- sodium fluoride paste
Universal Distribution Center LLC

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.

ADVANCED WHITENING ANTI-CAVITY FLUORIDE TOOTHPASTE

Active Ingredient

Sodium Fluoride (0.15% w/v fluoride ion)

Purpose

Anticavity

Uses

- builds increasing protection against painful sensitivity of teeth due to cold, heat, acids, sweets or contact.
- aids in the prevention of dental cavities.

Warning

When using this product

- if pain\ sensitivity still persists after 4 weeks of use, please visit your dentist.

Stop and ask a dentist

- if the problem persists or worsens.

Sensitivity teeth may indicate a serious problem that may need prompt care by a dentist.

Keep out of reach of children

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

Directions

Adults and Children 12 years of age and older:

- apply at least a 1-inch strip of product onto soft bristle toothbrush
- brush teeth thoroughly for at least 1 minute twice a day (morning and evening), and not more than 3 times day, or as recommended by a dentist or doctor.
- make sure to brush all sensitive areas of the teeth. Minimize swallowing. Spit out after brushing.

Children under 12 years of age: Consult a dentist or doctor.

Other information

- store in a cool, dry place.

Inactive Ingredients

calcium carbonate, FD&C blue#1, flavor, methylparaben, poly ethylene glycol 400, propylparaben, sodium carboxymethyl cellulose, sodium lauryl sulfate, sodium saccharin, sodium silicate, sorbitol, precipited silica, tetra sodium pyrophosphate, titanium dioxide, water.

PRINCIPAL DISPLAY PANEL

ADVANCED WHITENING ANTI-CAVITY FLUORIDE TOOTHPASTE

ADVANCED WHITENING ANTI CAVITY FLUORIDE

sodium fluoride paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52000-035
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM CARBONATE (UNII: H0G9379FGK)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM SILICATE (UNII: IJF18F77L3)	
SORBITOL (UNII: 506T60A25R)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-035-46	1 in 1 BOX	06/21/2017	
1		181 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 final	part355	06/21/2017	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Universal Distribution Center LLC (019180459)

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou Holyshine Industrial Co. Ltd		421141948	manufacture(52000-035)

Revised: 6/2017 Universal Distribution Center LLC