ANTI CAVITY FLUORIDE- sodium monofluorophosphate 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.

ANTI-CAVITY FLUORIDE TOOTHPASTE

Active Ingredient

Sodium Monofluorophosphate 0.76%

(Total Fluoride Content - 1000 ppm approx.)

Purpose

Anticavity toothpaste

Uses

- regular brushing with flouride toothpaste helps protect teeth againts 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 under 6 years of age

- If accidentally swallowed get medical help or contact a Poison Control Center right away.

Directions

- adults and children of 6 years and older: brush teeth thoroughly, after meals or at least twice a day, or as directed by a dentist.
- do not swallow.
- to minimize swallowing, use pea-sized amount in children under 6 years old.
- supervise child's brushing until good habits are established.
- children under 2 years: ask a dentist before use.

Other information

- store in a cool, dry place.

Inactive Ingredients

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

PRINCIPAL DISPLAY PANEL

ANTI-CAVITY FLUORIDE TOOTHPASTE

ANTI CAVITY FLUORIDE

sodium monofluorophosphate paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52000-036
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	7.6 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM CARBONATE (UNII: H0G9379FGK)	
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:52000-036-46	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(52000-036)

Revised: 6/2017 Universal Distribution Center LLC