

PLAK SMACKER ANTI CAVITY FLUORIDE- sodium fluoride paste
Yangzhou Hongshengding Chemical 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.

Plak Smacker GREAT WHITE SHARK ANTI-CAVITY FLUORIDE GEL TOOTHPASTE

Active ingredients

Sodium Fluoride 0.24%(0.14% w/v Fluoride ion)

Purpose

anticavity toothpaste

Uses

help aids in the prevention of dental 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 2years 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.

Do not swallow

to minimize swallowing use a peasized amount in children under 6

instruct children under 6 years oa age in good brushing and rinsing habits.

supervise children as necessary until capable of using without supervision

INACTIVE INGREDIENT

Sorbitol,Water ,Hydreated silica,PEG1500,Sodium Lauryl Sulfate,Flavor ,Sodium Carboxy Methyl Cellulose ,Sodium Saccharin,Sodium Benzoate,Blue1



Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 0.24% (0.14% w/v fluoride ion)	Anticavity toothpaste

Uses Helps aid in the prevention of dental cavities.

Warnings
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.

Do not use if inner foil is torn, cut or missing.

- 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.
 - Do not swallow
 - To minimize swallowing use a pea-sized amount in children under 6
 - Instruct children under 6 years of age in good brushing and rinsing habits
 - Supervise children as necessary until capable of using without supervision

Inactive Ingredients
 Sorbitol, Water, Hydrated Silica, PEG1500, Sodium Lauryl Sulfate, Flavor, Sodium Carboxy Methyl Cellulose, Sodium Saccharin, Sodium Benzoate, Sodium Fluoride, Blue 1

Questions or comments?
 1-800-558-6684

Distributed by: **PLAK SMACKER®**
 2260 Wendt St. Item# 00157
 Algonquin, IL 60102 Made in China
 (800) 558-6684 www.plaksmacker.com

PLAK SMACKER ANTI CAVITY FLUORIDE

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71035-600
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.24 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
DISODIUM ETHYLENE DIMYRISTAMIDE PEG-15 DISULFATE (UNII: X2CDV8U82V)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0K00R)	
DISODIUM CARBOXYMETHYLARSONATE (UNII: T9HTL93NB7)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71035-600-01	4 in 1 CARTON	02/11/2016	
1		144 in 1 BOX		
1		24 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71035-600-02	6 in 1 CARTON	02/11/2016	
2		12 in 1 BOX		
2		120 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	02/11/2016	

Labeler - Yangzhou Hongshengding Chemical Co.,Ltd. (543774755)**Registrant** - Yangzhou Hongshengding Chemical Co.,Ltd. (543774755)**Establishment**

Name	Address	ID/FEI	Business Operations
Yangzhou Hongshengding Chemical Co.,Ltd.		543774755	manufacture(71035-600)

Revised: 1/2018

Yangzhou Hongshengding Chemical Co.,Ltd.