

PLAK SMACKER ANTI-CAVITY FLUORIDE GEL- sodium fluoride paste
HUAIAN ZONGHENG BIO-TECH 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.

71167-005 PLAK SMACKER 0.24

Active Ingredient

sodium fluoride 0.24%±0.14% w/v fluoride ion

Purpose

Anticavitytoothpaste

Use

helps aid in the prevention of dental cavities.

Warning

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.

Directions

Adults and children 6 years of age and older:brush teeth thoroughly, after meals or at least twice a day or use as directed by a dentist.

do not swallow

to minimize swallowing use a pea-sized amount in children under 6

supervise children as necessary until capable of using without supervision

Inactive Ingredients

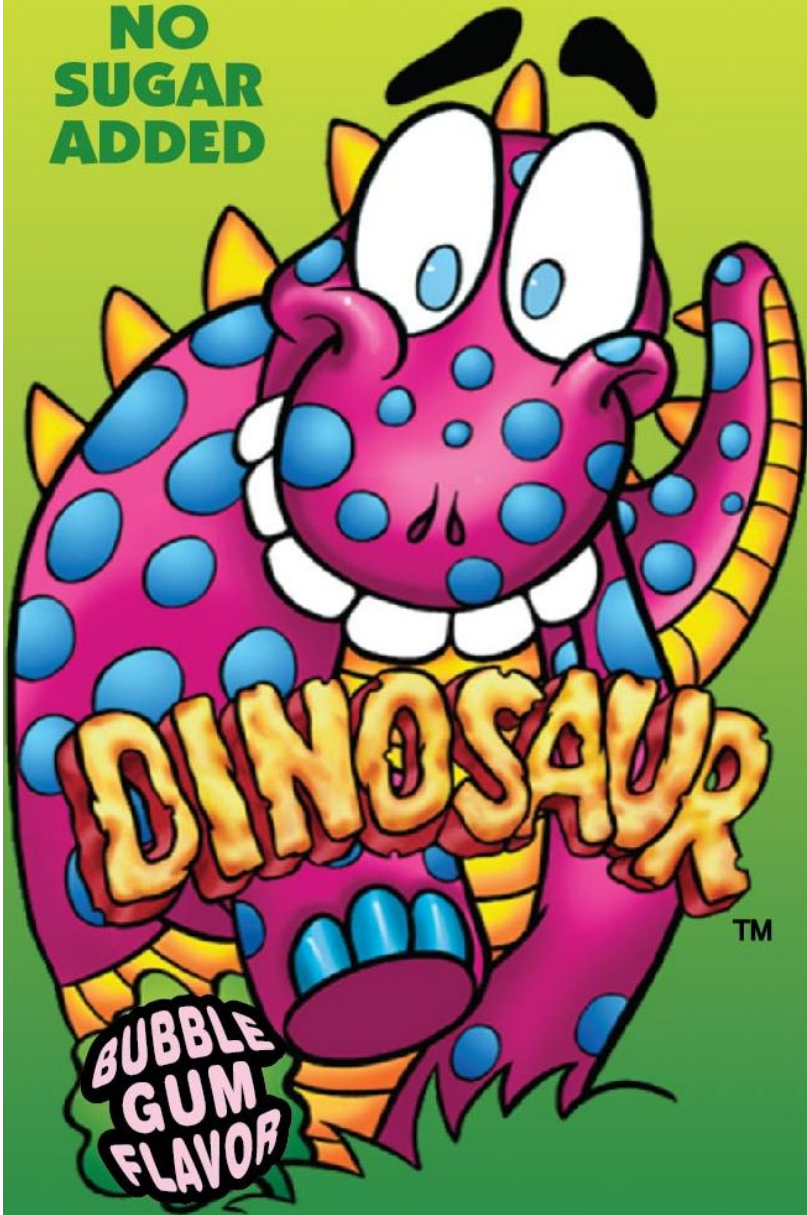
sorbitl,water,silicon dioxide,glycerin,saccharin sodium,PEG-8,sodium carboxymethyl cellulose ,lauryl sodium sulfate,aroma,sodium benzoate,ci42090anium Dioxide),Sodium saccharin,rose canina fruit oil

Keep out of reach of children under 6 years of age

Keep out of reach of children under 6 years of age

PLAK SMACKER®

**NO
SUGAR
ADDED**



**ANTI-CAVITY FLUORIDE GEL TOOTHPASTE
NET WT. .85oz (24g)**

Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 0.24% (0.14% w/v fluoride ion)	Anticavit 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 years.
- 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, Silicon Dioxide, Glycerin, Saccharin Sodium, PEG-8, Sodium Carboxymethyl Cellulose, Lauryl Sodium Sulfate, Aroma, Sodium Benzoate, C142090, C116035

Questions or comments?

1-800-558-6684

Distributed by: **PLAK SMACKER®**

2260 Wendt St.

Algonquin, IL 60102

(800) 558-6684

Item# 10004

Made in China

www.plaksmacker.com



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 2260 Wendt St. Item# 100050
 Algonquin, IL 60102 Made in China
 (800) 558-6684 www.plaksmacker.com

PLAK SMACKER ANTI-CAVITY FLUORIDE GEL

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71167-005
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
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL, L- (UNII: 01Q0586BG1)	
WATER (UNII: 059QF0K00R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-8 DIOLEATE (UNII: 6JR5A7273E)	
DISODIUM CARBOXYMETHYLARSONATE (UNII: T9HTL93NB7)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
AROMADENDRIN (UNII: 7YA4640575)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71167-005-01	144 in 1 CARTON	02/02/2018	
1		24 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71167-005-02	120 in 1 CARTON	02/02/2018	
2		24 in 1 BOX		
2		28 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:71167-005-04	144 in 1 CARTON	02/02/2018	
3		50 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:71167-005-05	72 in 1 CARTON	02/02/2018	
4		100 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:71167-005-06	144 in 1 BOX	02/02/2018	
5		100 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:71167-005-03	120 in 1 CARTON	02/02/2018	
6		24 in 1 BOX		
6		120 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:71167-005-07	480 in 1 BOX	02/02/2018	
7		28 g in 1 TUBE; Type 0: Not a Combination Product		
8	NDC:71167-005-08	72 in 1 BOX	02/02/2018	
8		120 g in 1 TUBE; Type 0: Not a Combination Product		
9	NDC:71167-005-09	144 in 1 BOX	02/02/2018	
9		120 g in 1 TUBE; Type 0: Not a Combination Product		
10	NDC:71167-005-10	288 in 1 BOX	02/02/2018	
10		50 g in 1 TUBE; Type 0: Not a Combination Product		
11	NDC:71167-005-11	480 in 1 CARTON	02/02/2018	
11		24 in 1 BOX		
11		28 g in 1 TUBE; Type 0: Not a Combination Product		
12	NDC:71167-005-12	576 in 1 CARTON	02/02/2018	
12		144 in 1 BOX		
12		24 g in 1 TUBE; Type 0: Not a Combination Product		

13	NDC:71167-005-13	72 in 1 CARTON	02/02/2018	
13		12 in 1 BOX		
13		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 final	part355		02/02/2018	

Labeler - HUIAN ZONGHENG BIO-TECH CO., LTD (527152733)

Establishment			
Name	Address	ID/FEI	Business Operations
HUIAN ZONGHENG BIO-TECH CO., LTD		527152733	manufacture(71167-005)

Revised: 3/2018

HUIAN ZONGHENG BIO-TECH CO., LTD