

**PLAK SMACKER GREAT WHITE SHARK COOL BERRY FLAVOR ANTI CAVITY
FLUORIDE GEL TOOTH- sodium fluoride paste, dentifrice
Yangzhou SION Commodity Co.,Ltd**

70766-012

Active ingredients

SODIUM FLUORIDE 0.24% (0.10 w/v Fluoride ion)

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Purpose

Anti-cavity toothpaste

Uses

Aids in the prevention of cavities.

Warnings

Keep out of the reach of children under 6 years of age. If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center immediately.

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

Keep out of reach of children.

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 physician
- Do not swallow
- To minimize wallowing, use a pea sizes amount in children under 6 years
- Supervise children's brushing until good habits are established
- Children under 2 years of age: consult a dentist or physician

INACTIVE INGREDIENT

Sorbitol, Water, Silica, PEG-400, Sodium lauryl sulfate, Cellulose gum, Xanthan gum, flavor, Xylitol, Sodium saccharin, Sodium benzoate, Trisodium phosphate, CI 42090

3mm
1mm
2.6mm

4mm
3*7mm



Drug Facts	
Active Ingredient	Purpose
Sodium Fluoride 0.24% (0.10% w/v fluoride ion) Anti-Cavity Toothpaste
Use Aids in the prevention of cavities.	
Warnings Keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center immediately.	
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 physician.	
■ Do not swallow. ■ To minimize swallowing use a pea sized amount in children under 6 years. ■ Supervise children's brushing until good habits are established. ■ Children under 2 years of age, consult a dentist or physician.	
Inactive Ingredients	
Sorbitol, Water, Silica, PEG-400, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Xanthan Gum, Xylitol, Sodium Saccharin, Sodium Benzoate, Trisodium Phosphate, CI 42090	
Questions or comments? 1-800-558-6684	

Distributed by:
Young Innovations, Inc. REF 100050
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Algonquin, IL 60102 USA
www.plaksmacker.com SHARK24G Rev.A

PLAK SMACKER GREAT WHITE SHARK COOL BERRY FLAVOR ANTI

CAVITY FLUORIDE GEL TOOTH

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70766-012
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TRISODIUM PHOSPHIDE (UNII: A360RQX9W2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
XYLITOL (UNII: VCQ006KQ1E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70766-012-01	144 in 1 BOX	01/04/2024	
1		24 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70766-012-02	5 in 1 CARTON	01/04/2024	
2		24 in 1 BOX		
2		28 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:70766-012-06	480 in 1 BOX	01/04/2024	
3		28 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:70766-012-03	144 in 1 BOX	01/04/2024	
4		50 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:70766-012-04	72 in 1 BOX	01/04/2024	
5		100 g in 1 TUBE; Type 0: Not a Combination Product		

6	NDC:70766-012-05	144 in 1 BOX	01/04/2024	
6		100 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:70766-012-07	72 in 1 BOX	01/04/2024	
7		120 g in 1 TUBE; Type 0: Not a Combination Product		
8	NDC:70766-012-08	144 in 1 BOX	01/04/2024	
8		120 g in 1 TUBE; Type 0: Not a Combination Product		
9	NDC:70766-012-09	12 in 1 BOX	01/04/2024	
9		119 g in 1 TUBE; Type 0: Not a Combination Product		
10	NDC:70766-012-10	72 in 1 CARTON	01/04/2024	
10		12 in 1 BOX		
10		119 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 Drug	M005	01/04/2024	

Labeler - Yangzhou SION Commodity Co.,Ltd (546806042)

Registrant - Yangzhou SION Commodity Co.,Ltd (546806042)

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou SION Commodity Co.,Ltd		546806042	manufacture(70766-012)

Revised: 7/2024

Yangzhou SION Commodity Co.,Ltd