

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

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**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 saccharine, Sodium benzoate, Trisodium phosphate, CI 42090

3mm  
1mm  
2.6mm  
wwg.z

4mm  
3\*7mm



## Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 0.24% .....	Anti-Cavity
(0.10% w/v fluoride ion) .....	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:  
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Algonquin, IL 60102 USA  
www.plaksmacker.com

REF 100050

Made in China

SHARK24G Rev.A

PLAK SMACKER GREAT WHITE SHARK COOL BERRY FLAVOR ANTI

# CAVITY FLUORIDE GEL TOOTH

sodium fluoride paste, dentifrice

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## 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: 1/2024

Yangzhou SION Commodity Co.,Ltd