

**PLAK SMACKER- stannous fluoride gel**  
**Dental Technologies, Inc.**

*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.*

-----

**Drug Facts**

**Active Ingredient**

Stannous Fluoride 0.4%

**Purpose**

Anticavity

**Uses**

Helps aid in the prevention of dental cavities.

**Warnings:**

**This is an anticavity fluoride preventive treatment gel, not a toothpaste.**

Read directions carefully before using.

When using this product it may produce surface staining of the teeth. Adequate tooth brushing may prevent these stains which are not harmful to permanent and may be removed by your dentist.

**Keep out of reach of children.**

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: Use once a day after brushing your teeth with a toothpaste. Apply the gel to your teeth and brush thoroughly. Allow the gel to remain on your teeth for 1 minute and then spit out. Do not swallow the gel. Do not eat or drink for 30 minutes after brushing.
- Instruct children under 12 years of age in the use of this product (to minimize swallowing). Supervise children as necessary until capable of using without supervision.
- Children under 6 years of age: Consult a dentist or doctor.

**Other Information**

Do not use if the foil seal under the cap is torn, cut or missing.

**Inactive Ingredients:**

Ascorbic Acid, Carbomer, Citric Acid, Flavor, Glycerin, Triethanolamine

**Questions or comments?**

1-800-558-6684

**DISTRIBUTED BY**

**PLAK SMACKER®**

**2260 Wendt St**

**Algonquin, IL 60102**

**www.plaksmacker.com**

**Principal Display Panel**

HOME CARE

FLUORIDE GEL

0.4% STANNOUS FLUORIDE

Savory Strawberry

11427

AIDS IN THE

PREVENTION

OF DENTAL CAVITIES

PLAK SMACKER

NET WEIGHT - 4.3 oz. (121.9g)

# Home Care Fluoride Gel

0.4% Stannous Fluoride



AIDS IN THE  
PREVENTION  
OF DENTAL CAVITIES



Net Weight 4.3 oz (121.9 g)

## Drug Facts

Active ingredient	Purpose
Stannous Fluoride 0.4%.....	Anticavity

**Uses** Helps aid in the prevention of dental cavities.

### Warnings

This is an anticavity fluoride preventive treatment gel, not a toothpaste. Read directions carefully before using.

**When using this product** it may produce surface staining of the teeth. Adequate tooth brushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.

**Keep out of reach of children.** 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: Use once a day after brushing your teeth with a toothpaste. Apply the gel to your teeth and brush thoroughly. Allow the gel to remain on your teeth for 1 minute and then spit out. Do not swallow the gel. Do not eat or drink for 30 minutes after brushing.
- Instruct children under 12 years of age in the use of this product (to minimize swallowing). Supervise children as necessary until capable of using without supervision.
- Children under 6 years of age: Consult a dentist or doctor.

### Other information

Do not use if the foil seal under the cap is torn, cut or missing.

### Inactive Ingredients

Ascorbic Acid, Carbomer, Citric Acid, Flavor, Glycerin, Triethanolamine

### Questions or comments?

1-800-558-6684

DISTRIBUTED BY

PLAK SMACKER  
2260 Wendt St  
Algonquin, IL 60102  
[www.plaksmacker.com](http://www.plaksmacker.com)



**PLAK SMACKER**

stannous fluoride gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55346-0414
<b>Route of Administration</b>	DENTAL, ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.969 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CARBOMER 934 (UNII: Z135WT9208)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	STRAWBERRY (Savory Strawberry)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55346-0414-2	121.9 g in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part355	12/31/2007	

**Labeler** - Dental Technologies, Inc. (148312838)