

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 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

Principal Display Panel

Home Care

Fluoride Gel

0.4% Stannous Fluoride

Bubblegum Burst

11422

AIDS IN THE

PREVENTION

OF DENTAL CAVITIES

PLAK SMACKER

Net Weight 4.3 oz. (121.9g)

Home Care Fluoride Gel

0.4% Stannous Fluoride



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PREVENTION
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DISTRIBUTED BY

PLAK SMACKER
2260 Wendt St
Algonquin, IL 60102
www.plaksmacker.com



PLAK SMACKER

stannous fluoride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55346-0412
Route of Administration	DENTAL, ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM (Bubblegum Burst)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55346-0412-2	121.9 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	12/31/2007	

Labeler - Dental Technologies, Inc. (148312838)