

**CLEARARC- stannous fluoride gel gel**  
**Den-Mat Holdings, LLC**

*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.*

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**Active ingredient**

Stannous Fluoride 0.4% (0.12% w/v fluoride ion)

**Purpose**

Anticavity

**Uses**

Aids in the prevention of dental cavities.

**Warnings**

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

Using this product may produce surface staining of the teeth. Adequate tooth brushing may prevent stains which are not harmful or permanent and may be removed by a dentist.

**Keep out of reach of children section**

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 and older: Use once daily after brushing.
- Apply a thin line of gel to each custom tray. Place firmly over teeth. After wearing trays for 1 minute, remove and spit out any remaining gel. Do not swallow. Do not eat or drink for 30 minutes.
- Instruct children under 12, in the use of this product (to minimize swallowing). Supervise children as necessary until capable of using without supervision.
- Children under 6, consult a dentist or doctor.

**Other Information**

For your protection, do not use if the tip under the cap is cut or tampered.

**Inactive Ingredients**

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

**Questions or Comments?**

877-9-CLEARARC

**Principal Display Panel**

ClearArc®

Clinical Strength

Cavity Protection Gel

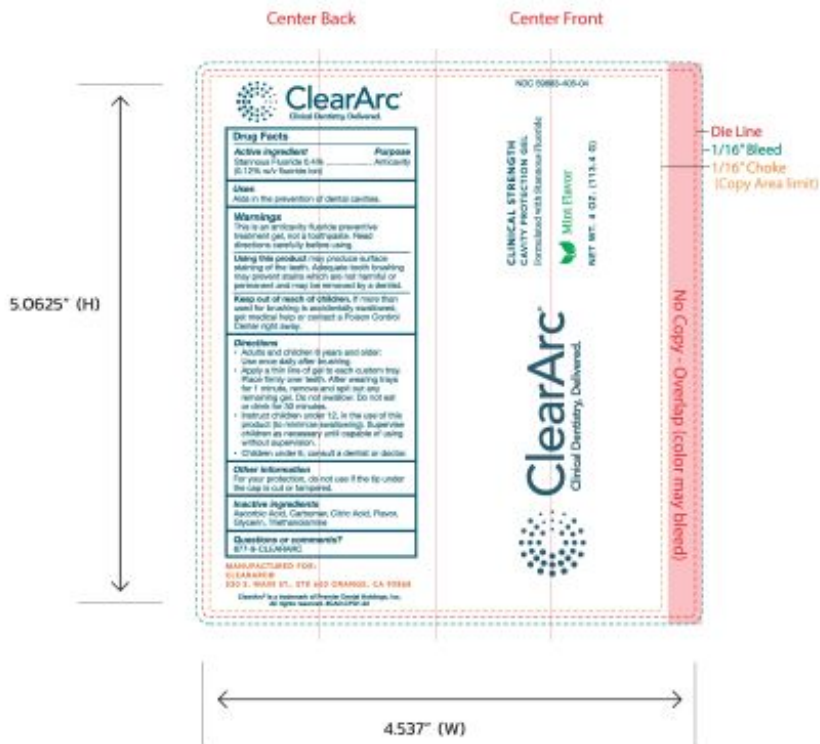
Formulated with Stannous Fluoride

Mint Flavor

NET WT. 4 OZ. (113.4 G)

**Labeling**

Dental Tech 3oz Overlap - not through crimp



**DIE LINE SPECIFICATIONS**

SHAPE: Rectangle  
 SIZE: 5.0625" (H) x 4.537" (W)  
 CORNER RADIUS: .0625 in  
 COPY POSITION #3

**INFO LABEL** INNOVATIVE PACKAGING SOLUTIONS

# CLEARARC

stannous fluoride gel gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59883-405
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>STANNOUS FLUORIDE</b> (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.969 mg in 1 g

## Inactive Ingredients

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

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59883-405-04	113.4 g in 1 TUBE; Type 0: Not a Combination Product	07/07/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/07/2022	

**Labeler** - Den-Mat Holdings, LLC (809857704)

### Establishment

Name	Address	ID/FEI	Business Operations
Dental Technologies , Inc		148312838	manufacture(59883-405) , pack(59883-405) , label(59883-405)

Revised: 6/2022

Den-Mat Holdings, LLC