

# STANCE- 0.63% stannous fluoride concentrate rinse rinse Elevate Oral Care

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## Stance 0.63% Stannous Fluoride Concentrate Rinse Tropical Breeze

### Active Ingredients

<i>Active ingredient</i>	<i>Purpose</i>
Stannous fluoride 0.63% concentrate (0.19% w/v fluoride ion)	.....anticavity, antigingivitis, antihypersensitivity

### Uses Indications

**Uses** ■ aids in the prevention of dental decay ■ helps prevent gingivitis ■ helps control plaque bacteria ■ builds increasing protection against painful tooth sensitivity

### Warnings

**Warnings**  
■ when using this product, do not use for sensitivity longer than four weeks unless recommended by a dentist ■ stop use and ask a dentist if sensitivity persists or worsens because sensitive teeth may indicate a serious problem that may need prompt care  
**Keep out of reach of children.** If more than used for rinsing is accidentally swallowed, seek medical attention or contact a Poison Control Center immediately.

### Keep Out of Reach of Children

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### Directions Instructions for Use

<b>Directions</b>	
adults and children 6 years of age and older:	<ul style="list-style-type: none"> <li>■ do not use before mixing with water - use immediately after preparing</li> <li>■ use once daily after brushing your teeth with toothpaste or as directed by your dentist</li> <li>■ remove cap and replace with pump</li> <li>■ rotate spout to extend</li> <li>■ prime the pump</li> <li>■ make 2 complete pump depressions into cup provided (1/8 oz)</li> <li>■ add water to line (1 oz) on cup</li> <li>■ close cap and shake to mix</li> <li>■ swish 1/2 oz for one minute then spit and repeat</li> <li>■ do not swallow the rinse</li> <li>■ do not eat or drink for 30 minutes after use</li> </ul>
children under 6 years of age:	<ul style="list-style-type: none"> <li>■ instruct children under 12 years of age in good rinsing habits (to minimize swallowing)</li> <li>■ supervise children as necessary until capable of using without supervision</li> </ul>
children under 6 years of age:	<ul style="list-style-type: none"> <li>■ consult a dentist or doctor</li> </ul>

## Inactive Ingredients

*Inactive ingredients* flavor, glycerin, xylitol

## Questions

*Questions or comments? 1-877-866-9113*

## Dosage and Administration

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## Other Information

Drugs Facts	
<b>Active ingredient</b>	<b>Purpose</b>
Stannous fluoride 0.63% concentrate (0.19% w/v fluoride ion)	.....antitartar, anti-gingivitis, antihypersensitivity
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<b>Other information</b>	
<ul style="list-style-type: none"> <li>products containing stannous fluoride may produce surface staining of the teeth</li> <li>adequate toothbrushing may prevent these stains which are not harmful and may be removed by your dentist</li> <li>see your dentist regularly</li> <li>for professional use only</li> <li>this product is not intended for at-home or unsupervised use</li> <li>Store at (23°C±2°C)</li> </ul>	
<b>Inactive ingredients</b> flavor, glycerin, xylitol	
Questions or comments? 1-877-866-9113	

## Tropical Breeze Flavor

10% Xylitol • Alcohol-Free



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Antimicrobial Oral Rinse

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Questions/Comments:  
1-877-866-9113  
Visit [www.elevateoralcare.com](http://www.elevateoralcare.com)

Manufactured for:  
Elevate Oral Care, LLC  
in the USA  
345 Pine Road, Suite 5  
West Palm Beach, FL 33411

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ELE387-092923

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Elevate Oral Care, LLC.

Important: Read directions thoroughly

Contents: 1 Bottle  
NET WT. 10 oz 283.5 g

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## Primary PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

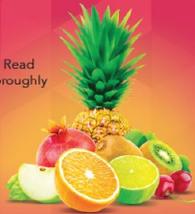
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NDC57511-0202-1

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Antimicrobial Oral Rinse

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0.63% stannous fluoride concentrate rinse

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57511-0202
<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:Q80VPU408O)	FLUORIDE ION	1.2 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>	ROUND	<b>Size</b>	
<b>Flavor</b>	FRUIT (Tropical Breeze)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57511-0202-1	225 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/25/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	08/25/2016	

**Labeler** - Elevate Oral Care (002863526)

**Registrant** - Elevate Oral Care (002863526)

### Establishment

Name	Address	ID/FEI	Business Operations
Elevate Oral Care		002863526	manufacture(57511-0202)