

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

*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.*

### Stance 0.63% Stannous Fluoride Concentrate Rinse Mint

#### OTC - ACTIVE INGREDIENT SECTION

##### Stannous Fluoride 0.63% Rinse Concentrate

**Drug Facts**

Active ingredient	Purpose
Stannous fluoride 0.63% concentrate (0.12% w/v fluoride ion)	antitartar, antigingivitis, antihypersensitivity

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

**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.

**Directions**  
adults and children 6 years of age and older:  
• do not use before mixing with water  
• use immediately after preparing rinse  
• use once daily after brushing your teeth with a toothpaste or as directed by your dentist  
• remove cap and replace with pump  
• rotate spout counter clockwise to extend  
• depress pump until medicine comes to the tip of the pump  
• make 2 complete pump depressions into cup provided (1/8 oz)  
• add tap water to line (1 oz) on cup  
• close cap and shake to mix  
• vigorously swish 1/2 oz for one minute then spit out and repeat with second 1/2 oz  
• do not swallow the rinse  
• do not eat or drink for 30 minutes after rinsing  
• instruct children under 12 years of age in good rinsing habits (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**  
• products containing stannous fluoride may produce surface staining of the teeth  
• adequate toothbrushing may prevent these stains which are not harmful and may be removed by your dentist  
• see your dentist regularly

**Inactive ingredients** glycerin, xylitol, flavor

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

**Stance™**  
0.63% Stannous Fluoride Concentrate  
Antimicrobial Oral Rinse  
Mint Flavor

**Stance™**  
0.63% Stannous Fluoride Concentrate  
Antimicrobial Oral Rinse  
Mint Flavor

**Stance™**  
0.63% Stannous Fluoride Concentrate  
Antimicrobial Oral Rinse  
Mint Flavor

**WITH 10% Xylitol**

**Alcohol Free**  
**Important:**  
Read directions thoroughly.

**Contents:**  
**1 Bottle**  
NET WT. 10 oz. 283.5 g

Made in U.S.A. for Elevate Oral Care  
West Palm Beach, FL 33411  
[www.elevateoralcare.com](http://www.elevateoralcare.com)  
Elevate and Stance are trademarks of Elevate Oral Care, LLC.  
© Elevate Oral Care 2016. All Rights Reserved. ELE0378-0616

## **INDICATIONS & USAGE SECTION**

Uses • aids in the prevention of dental decay

- helps prevent gingivitis • helps control plaque bacteria
- builds increasing protection against painful tooth sensitivity

## **WARNINGS SECTION**

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 infants and children.

## **INSTRUCTIONS FOR USE SECTION**

Directions

Adults and 6 years of age and older:

- do not use before mixing with water
- use immediately after preparing rinse
- use once daily after brushing your teeth with a toothpaste or as directed by your dentist
- remove cap and replace with pump
- rotate spout counter clockwise to extend
- depress pump until medicine comes to the tip of the pump
- make 2 complete pump depressions into cup provided (1/8 oz)
- add tap water to line (1 oz) on cup
- close cap and shake to mix
- vigorously swish 1/2 oz for one minute then spit out and repeat with second 1/2 oz
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
- supervise children as necessary until capable of using without supervision

Children under 6 years of age

- consult a dentist or doctor

## **INACTIVE INGREDIENT SECTION**

Inactive ingredients glycerin, xylitol, flavor

## **OTC - QUESTIONS SECTION**

Questions? 1-877-866-9113 or visit our website at [www.elevateoralcare.com](http://www.elevateoralcare.com)

## Dosage and Administration

make 2 complete pump depressions into cup  
provided (1/8 oz)

- add tap water to line (1 oz) on cup
- close cap and shake to mix
- vigorously swish 1/2 oz for one minute then spit out and repeat with second 1/2 oz
- do not swallow the rinse
- aids in the prevention of dental decay
- helps prevent gingivitis • helps control plaque bacteria
- builds increasing protection against painful tooth sensitivity

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Stannous Fluoride 0.63% Rinse Concentrate

**Directions (Continued)**  
adults and children 6 years of age and older:

- add tap water to line (1 oz) on cup
- close cap and shake to mix
- vigorously swish with 1/2 oz for one minute then spit out and repeat with second 1/2 oz
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- instruct children under 12 years of age in good rinsing habits (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**

- products containing stannous fluoride may produce surface staining of the teeth
- adequate toothbrushing may prevent these stains which are not harmful and may be removed by your dentist
- see your dentist regularly

**Inactive ingredients** glycerin, xylitol, flavor

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

Elevate and Stance are trademarks of Elevate Oral Care, LLC.  
© Elevate Oral Care 2016. All Rights Reserved. ELE0379-0816

**Mint**  
57511-0201-1

**Stance™**  
0.63% Stannous Fluoride Concentrate  
**Antimicrobial Oral Rinse**

WITH  
10%  
Xylitol



**Alcohol Free**  
**Important:** Read directions thoroughly.  
NET WT. 10 oz. 283.5 g

**Drug Facts**

<b>Active ingredient</b> Stannous fluoride 0.63% concentrate ..... (0.12% w/v fluoride ion)	<b>Purpose</b> anticavity, antigingivitis, antihypersensitivity
<b>Uses</b> • aids in the prevention of dental decay • helps prevent gingivitis • helps control plaque bacteria • builds increasing protection against painful tooth sensitivity	
<b>Warnings</b> <ul style="list-style-type: none"><li>• when using this product do not use for sensitivity longer than four weeks unless recommended by a dentist</li><li>• stop use and ask a dentist if sensitivity persists or worsens because sensitive teeth may indicate a serious problem that may need prompt care</li></ul>	
<b>Keep out of reach of children.</b> If more than used for rinsing is accidentally swallowed, seek medical attention or contact a Poison Control Center immediately.	
<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</li><li>• use immediately after preparing rinse</li><li>• use once daily after brushing your teeth with a toothpaste or as directed by your dentist</li><li>• remove cap and replace with pump</li><li>• rotate spout counter clockwise to extend</li><li>• depress pump until medicine comes to the tip of the pump</li><li>• make 2 complete pump depressions into cup provided (1/8 oz)</li></ul>	

## STANCE

0.63% stannous fluoride concentrate rinse

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57511-0201
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.2 mg in 1 mL

### Inactive Ingredients

Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)				
XYLITOL (UNII: VCQ006KQ1E)				
Product Characteristics				
Color			Score	
Shape		ROUND	Size	
Flavor		MINT	Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57511-0201-1	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 final		part355	08/25/2016	

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

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

Establishment			
Name	Address	ID/FEI	Business Operations
Elevate Oral Care		002863526	repack(57511-0201)