

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

Stance 0.63% Stannous Fluoride Concentrate Rinse Tropical Breeze

OTC - ACTIVE INGREDIENT SECTION

Stannous Fluoride 0.63% Concentrate Rinse

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.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of infants and children.

INSTRUCTIONS FOR USE SECTION

Directions

Adults and Children 6 years 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:

- 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

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PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Stannous Fluoride 0.63% Rinse Concentrate

Directions (Continued)

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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

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elevate
ORAL CARE

Tropical Breeze

57511-0202-1

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

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

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STANCE

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57511-0202
Route of Administration	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	FRUIT (Tropical Breeze)	Imprint Code	
Contains			

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)

