

STANCE- 0.63% stannous fluoride concentrate rinse Elevate Oral Care

Stance 0.63% Stannous Fluoride Concentrate Rinse Mint

OTC - ACTIVE INGREDIENT SECTION

Stannous Fluoride 0.63% Rinse Concentrate

Drug Facts

Active ingredient Stannous fluoride 0.63% concentrate (0.12% w/v fluoride ion) **Purpose** antiscav, 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

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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
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INDICATIONS & USAGE SECTION

Uses • aids in the prevention of dental decay

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WARNINGS SECTION

Warnings

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Keep out of reach of infants and children.

INSTRUCTIONS FOR USE SECTION

Directions

Adults and 6 years of age and older:

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Children under 6 years of age

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INACTIVE INGREDIENT SECTION

Inactive ingredients glycerin, xylitol, flavor

OTC - QUESTIONS SECTION

Questions? 1-877-866-9113 or visit our website at 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
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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)
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children under 6 years of age:

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Other information

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StanceTM
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Antimicrobial Oral Rinse

WITH 10% Xylitol

Alcohol Free
Important: Read directions thoroughly.
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STANCE

0.63% stannous fluoride concentrate rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57511-0201
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	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 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(57511-0201)