

**FLUORIMAX 5000 SENSITIVE- 1.1% sodium fluoride with 5% potassium nitrate toothpaste paste, dentifrice Elevate Oral Care**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**FluoriMax 5000 1.1% Sodium Fluoride & 5% Potassium Nitrate Toothpaste**

**OTC - ACTIVE INGREDIENT SECTION**

Sodium Fluoride 1.1% Anticavity

Potassium Nitrate 5% Antisensitivity

**INDICATIONS & USAGE SECTION**

A dental caries preventive and sensitive teeth toothpaste for once daily self applied topical use. It is well established that 1.1% sodium fluoride is safe and effective as a caries preventive when applied frequently with mouthpiece applicators. Use once daily in place of your regular toothpaste unless otherwise instructed by your dental professional.

**WARNINGS SECTION**

Prolonged daily ingestion may result in various degrees of dental fluorosis in pediatric patients under age 6 years, especially if water fluoridation exceeds 0.7 ppm, since younger patients frequently cannot perform the brushing process without significant swallowing. Use in pediatric patients under age 6 requires special supervision to prevent repeated swallowing of dental cream which could cause dental fluorosis. Read instructions carefully before using. Keep out of reach of infants and children.

**OTC - KEEP OUT OF REACH OF CHILDREN SECTION**

Keep out of reach of infants and children.

**INSTRUCTIONS FOR USE SECTION**

Directions: \*adults and children 2 years and older: wet a toothbrush and apply a pea-sized (~0.25 gram) amount of toothpaste onto a toothbrush \* brush thoroughly after meals or at least twice a day or use as directed by a dentist or physician. \* to minimize swallowing, only dispense a pea-sized amount for children under 6 years. \* supervise children's brushing until good habits are established. \* children under 2 years: ask dentist or physician.

**INACTIVE INGREDIENT SECTION**

Inactive ingredients; sorbitol, deionized water, hydrated silica, xylitol, glycerin, PEG 400, sodium lauryl sulfate, potassium phosphate monobasic, titanium dioxide, vanilla mint

flavor, sodium saccharin

## OTC - QUESTIONS SECTION

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

## OTC - PURPOSE SECTION

Helps protect against Cavities and relieve dentinal hypersensitivity

## DOSAGE & ADMINISTRATION SECTION

Directions: adults and pediatric patients 6 and older, apply a thin ribbon of FluoriMax toothpaste to a toothbrush. Brush thoroughly once daily for two minutes, preferably at bed time. After use, adults spit, do not eat, drink or rinse for 30 minutes. Pediatric patients 6-16 spit after use and rinse mouth thoroughly.

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

N 57511-0102-3

elevate **SENSITIVE**  
**FluoriMax™ 5000**  
1.1% Sodium Fluoride

**Rx Only | NET WT. 3.4 oz (96 g)**

**Spearmint**  
with **10%**  
**Xylitol**

**INDICATIONS:** A dental caries preventive and sensitive teeth toothpaste; for twice daily self-applied topical use.

**ACTIVE INGREDIENTS:** Potassium Nitrate 5.0%, Sodium Fluoride 1.1% (5000 ppm fluoride)

**DIRECTIONS FOR USE:** This prescription toothpaste is recommended for adults and children 12 years of age and older. For patients under age 12 consult a dental professional. Use daily in place of a conventional toothpaste. Follow these instructions unless otherwise instructed by a dentist or physician.

1. Apply a thin ribbon of FluoriMax™ 5000 Sensitive Toothpaste to toothbrush and brush teeth thoroughly for two minutes.

2. After brushing, adults should spit, but not rinse. Children should spit after brushing and then rinse mouth thoroughly with water.

FluoriMax 5000 Sensitive Toothpaste can be used in place of your regular toothpaste based on the recommendation of your dentist or physician.

**WARNINGS: DO NOT SWALLOW. Keep out of reach of children under 12 years of age.** Read all instructions and prescribing information before using this product. Do not freeze or expose to extreme heat.

**Note:** Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or physician.

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

Made in U.S.A. for  
**Elevate Oral Care, LLC**  
West Palm Beach, FL 33411

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# FLUORIMAX 5000 SENSITIVE

1.1% sodium fluoride with 5% potassium nitrate toothpaste paste, dentifrice

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57511-0102
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>POTASSIUM NITRATE</b> (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	1.1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>SACCHARIN</b> (UNII: FST467XS7D)	
<b>POTASSIUM PHOSPHATE, MONOBASIC</b> (UNII: 4J9FJ0HL51)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>	ROUND	<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:57511-0102-3	96 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2017	10/31/2024

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2017	10/31/2024

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

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Elevate Oral Care		002863526	manufacture(57511-0102)

Revised: 10/2022

Elevate Oral Care