

**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 Spearmint**

**Warnings**

**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.

**Directions**

**Instructions for Use**

**FluoriMax® 5000 Sensitive 1.1% Sodium Fluoride Prescription Toothpaste**

**DESCRIPTION:** Self-applied topical dentifrice containing 1.1% (w/w) Sodium Fluoride and 5% Potassium Nitrate for use in the prevention of caries and for sensitive teeth.

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

**INACTIVE INGREDIENTS:** Cellulose Gum, Glycerin, Hydrated Silica, Monobasic Potassium Phosphate, PEG-12, Sodium Lauryl Sulfate, Sodium Saccharin, Spearmint Flavor, Sorbitol, Titanium Dioxide, Water, Xylitol

**CLINICAL PHARMACOLOGY:** Frequent topical applications to the teeth of preparations having a relatively high fluoride content increase tooth resistance to acid dissolution and enhances penetration of the fluoride ion into tooth enamel. It is well established that 1.1% Sodium Fluoride is safe and effective as a caries preventive when applied frequently with mouthpiece applicators.

**INDICATIONS AND USAGE:** A dental caries preventive and sensitive teeth toothpaste for daily self-applied topical use. Use daily in place of your regular toothpaste unless otherwise instructed by your dental professional.

**CONTRAINDICATIONS:** Do not use in pediatric patients under age 12 years unless recommended by a dentist or physician.

**WARNINGS:** Prolonged daily ingestion may result in various degrees of dental fluorosis in pediatric patients under age 12 years, especially if the water fluoridation exceeds 0.7 ppm, since younger pediatric patients frequently cannot perform the brushing process without significant swallowing. Use in pediatric patients under age 12 requires special supervision to prevent repeated swallowing of dentifrice which could cause dental fluorosis. Read directions carefully before using. Keep out of reach of infants and children.

**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.

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### PRECAUTIONS:

**General:** Not for systemic treatment. Do not swallow.

**Pregnancy: Teratogenic Effects:** Pregnancy Category B. There are no adequate and well-controlled studies in pregnant women. However, epidemiological studies conducted in areas with high levels of naturally fluoridated water showed no increase in birth defects. Heavy exposure to fluoride during utero development may result in skeletal fluorosis which becomes evident in childhood.

**Nursing Mothers:** It is not known if fluoride is excreted in human milk. However, many drugs are excreted in human milk and caution should be exercised when products containing fluoride are administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in pediatric patients below the age of 12 years have not been established.

**OVER DOSAGE:** If less than 5 mg fluoride/kg body weight (i.e., more than 2.3 mg fluoride/lb body weight) have been ingested, give calcium (e.g., milk) orally to relieve gastrointestinal symptoms and observe for a few hours. If more than 5 mg fluoride/kg body weight (i.e., more than 2.3 mg fluoride/lb body weight) have been ingested, give calcium (e.g., milk) orally to relieve gastrointestinal symptoms and immediately seek medical assistance. A pea-sized dose (0.25 g) of FluoriMax<sup>®</sup> 5000 Sensitive Toothpaste contains approximately 1.24 mg fluoride.

**DOSAGE AND ADMINISTRATION:** 1. Adults and pediatric patients 12 years of age or older, apply a thin ribbon of FluoriMax<sup>®</sup> 5000 Sensitive Toothpaste to a toothbrush. Brush thoroughly daily for two minutes. 2. After use, adults spit, do not eat, drink, or rinse for 30 minutes. Pediatric patients, age 12-16, spit after use and rinse mouth thoroughly.

### HOW SUPPLIED:

Two 3.4 oz (96 g) NET WT. Tubes

NDC 57511-0503-2

**STORAGE:** Store at 23°C±2°C.

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## Package Label and Instructions for use

**INDICATIONS:** A dental caries preventive and sensitive teeth toothpaste.

**ACTIVE INGREDIENT:** 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. FluoriMax<sup>®</sup> 5000 Sensitive Toothpaste can be used in place of your regular toothpaste based on the recommendation of your dentist or physician. Follow these instructions unless otherwise instructed by a dentist or physician.

1. Apply a thin ribbon of FluoriMax<sup>®</sup> 5000 Sensitive Toothpaste to toothbrush and brush teeth thoroughly for two minutes.

2. After brushing, adults should spit, but do not eat, drink, or rinse for 30 minutes. Children should spit after brushing and then rinse mouth thoroughly with water.

**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)

Manufactured for  
Elevate Oral Care, LLC.



in U.S.A

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NDC 57511-0503-2



SENSITIVE  
**FluoriMax<sup>®</sup> 5000**

**Spearmint**

1.1% Sodium Fluoride

Prescription Strength Toothpaste

FluoriMax® 5000

1.1% Sodium Fluoride Anti-Cavity Toothpaste

- Delivers 4 1/2 times more fluoride than regular toothpaste
- Helps prevent and reverse root decay
- Can be used every day for gentle, effective cleaning
- Helps prevent and treat dental hypersensitivity

**SENSITIVE**  
**FluoriMax® 5000**

1.1% Sodium Fluoride

Prescription Strength Toothpaste

With 10% Xylitol

Rx Only | Twin Pack  
Net WT. 6.8 oz (192g)

6 month  
Treatment

NDC 57511-0503-2



**Spearmint**

With 10% Xylitol

Rx Only | Twin Pack  
Net WT. 6.8 oz (192g)

## FLUORIMAX 5000 SENSITIVE

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

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:57511-0503
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	1.1 g in 100 g
<b>POTASSIUM NITRATE</b> (UNII: RU45X2JNOZ) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
SACCHARIN (UNII: FST467XS7D)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
XYLITOL (UNII: VCQ006KQ1E)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

## Product Characteristics

Color	white	Score	
Shape	ROUND	Size	
Flavor	MINT	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57511-0503-2	2 in 1 BOX	06/15/2022	
1	NDC:57511-0503-1	96 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/15/2022	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Elevate Oral Care		002863526	manufacture(57511-0503)