

## **FLUORIMAX 5000- 1.1% sodium fluoride toothpaste paste, dentifrice 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.*

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### **FluoriMax 5000 1.1% Sodium Fluoride Toothapste**

#### **OTC - ACTIVE INGREDIENT SECTION**

Sodium Fluoride 1.1% Anticavity

#### **INDICATIONS & USAGE SECTION**

A dental caries preventive 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 pump once to apply a pea-sized (~0.35 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 pump once to 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

## 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.

### FluoriMax™ 1.1% Sodium Fluoride Prescription Toothpaste

**DESCRIPTION:** Self-applied topical dentifrice containing 1.1%(w/w) sodium fluoride for use in the prevention of dental caries.

**ACTIVE INGREDIENT:** Sodium Fluoride (NaF) 1.1% (w/w).

**INACTIVE INGREDIENTS:** Sorbitol, Deionized Water, Hydrated Silica, Xylitol, Glycerin, PEG 400, Sodium Lauryl Sulfate, Monobasic Potassium Phosphate, Titanium Dioxide, Vanilla Mint Flavor, Sodium Saccharin

**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.

**INDICATIONS AND USAGE:** A dental caries preventive 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.

**CONTRAINDICATIONS:** Do not use in pediatric patients under age 6 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 6 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 6 requires special supervision to prevent repeated swallowing of dental cream which could cause dental fluorosis. Read directions carefully before using. Keep out of reach of infants and children.

#### 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 in 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 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 6 years have not been established.

**OVERDOSAGE:** If less than 5 mg fluoride/kg body weight (i.e., less than 2.3 mg fluoride/lb body weight) have been ingested, give calcium (e.g., milk) orally to relieve gastrointestinal symptoms and observe for few hours. If more than 5mg 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 (0.25g) of FluoriMax toothpaste contains approximately 1.24 mg fluoride.

**DOSAGE AND ADMINISTRATION:** 1. Adults and pediatric patients 6 years of age or older, apply a thin ribbon of FluoriMax toothpaste to a toothbrush. Brush thoroughly once daily for two minutes, preferably at bedtime. 2. After use, adults spit, do not eat, drink, or rinse for 30 minutes. Pediatric patients, age 6-16, spit after use and rinse mouth thoroughly.

#### HOW SUPPLIED:

3.4 oz. (96g) net wt. tube

N 57511-0101-3

**STORAGE:** Store at Controlled Room Temperature, 20-25 degrees C (68-77 degrees F).

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## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

FluoriMax 5000 Fluoride Toothpaste Cavity Protection. Net Wt 3.4oz (96g)



5000 ppm Fluoride Toothpaste

N 57511-0101-3

# FluoriMax™

1.1% Sodium Fluoride

**Rx Only** • NET WT. 3.4 oz. (96 g)



Vanilla  
Mint

**INDICATIONS:** Topical fluoride for use in the prevention of dental caries.

**ACTIVE INGREDIENT:** Sodium Fluoride 1.1% (5000 ppm fluoride)

**DIRECTIONS FOR USE:** This prescription toothpaste is recommended for adults and children 6 years of age and older. 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™ 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 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 6 years of age.** Read all instructions and prescribing information before using this product. Do not freeze or expose to extreme heat.

**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

1.1% sodium fluoride toothpaste paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57511-0101
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	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: Y6O7T4G8P9)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<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:57511-0101-3	96 g in 1 TUBE; Type 0: Not a Combination Product	02/02/2015	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/01/2015	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Elevate Oral Care		002863526	manufacture(57511-0101)

Revised: 10/2021

Elevate Oral Care