

FLUORIMAX 5000- 1.1% sodium fluoride 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.

FluoriMax 5000 1.1% Sodium Fluoride Toothpaste Vanilla Mint Twin Pack

Warnings

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 dentifrice 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 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 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 6 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® 5000 Toothpaste contains approximately 1.24 mg fluoride.

Directions

Instructions For Use

FluoriMax® 5000 1.1% Sodium Fluoride Prescription Toothpaste

DESCRIPTION: Self-applied topical dentifrice containing 1.1% (w/w) Sodium Fluoride for use in the prevention of caries.

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

INACTIVE INGREDIENTS: Cellulose Gum, Glycerin, Hydrated Silica, Monobasic Potassium Phosphate, PEG-12, Sodium Lauryl Sulfate, Sodium Saccharin, Sorbitol, Titanium Dioxide, Vanilla Mint Flavor, 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 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 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 dentifrice which could cause dental fluorosis. Read directions carefully before using. Keep out of reach of infants and children.

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DOSAGE AND ADMINISTRATION: 1. Adults and pediatric patients 6 years of age or older, apply a thin ribbon of FluoriMax® 5000 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 6-16, spit after use and rinse mouth thoroughly.

HOW SUPPLIED:

Two 3.4 oz (96 g) NET WT. Tubes

NDC 57511-0504-2

STORAGE: Store at 23°C±2°C.

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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.

FluoriMax® 5000 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® 5000 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 6 years of age. Read all instructions and prescribing information before using this product. Do not freeze or expose to extreme heat.

FluoriMax® 5000

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
- Recommended by Dental Professionals

FluoriMax® 5000

1.1% Sodium Fluoride

Prescription Strength Toothpaste

Questions/Comments:

1-877-866-9113

Visit www.elevateoralcare.com

Manufactured for
Elevate Oral Care, LLC.



in U.S.A
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West Palm Beach, FL 33411
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ELE558.072023

NDC 57511-0504-2



Vanilla Mint

With 10% Xylitol

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

6 month

Treatment

NDC 57511-0504-2



Vanilla Mint

With 10% Xylitol

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

FLUORIMAX 5000

1.1% sodium fluoride toothpaste paste, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:57511-0504
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	1.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
SACCHARIN (UNII: FST467XS7D)	
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:57511-0504-2	2 in 1 BOX	06/15/2022	
1	NDC:57511-0504-1	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
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unapproved drug other		06/15/2022	
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Labeler - Elevate Oral Care (002863526)

Registrant - Elevate Oral Care (002863526)

Establishment

Name	Address	ID/FEI	Business Operations
Elevate Oral Care		002863526	manufacture(57511-0504)

Revised: 9/2025

Elevate Oral Care