

**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: 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.

Package Label and Instructions for use

INDICATIONS: A dental caries preventive and sensitive teeth toothpaste.

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

FluoriMax[®] 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste

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

Questions/Comments:
1-877-866-9113
Visit www.elevateoralcare.com

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Made in U.S.A for
Elevate Oral Care, LLC.
346 Pike Rd, Suite 5
West Palm Beach, FL 33411



N 57511-0504-2



FluoriMax[®] 5000 1.1% Sodium Fluoride

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

Vanilla Mint
with 10%
Xylitol

N 57511-0504-2



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1.1% Sodium Fluoride

Vanilla Mint
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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)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
SACCHARIN (UNII: FST467XS7D)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	

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
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(57511-0504)