FLUORIMAX 5000- 1.1% sodium fluoride toothpaste paste, dentifrice Elevate Oral Care

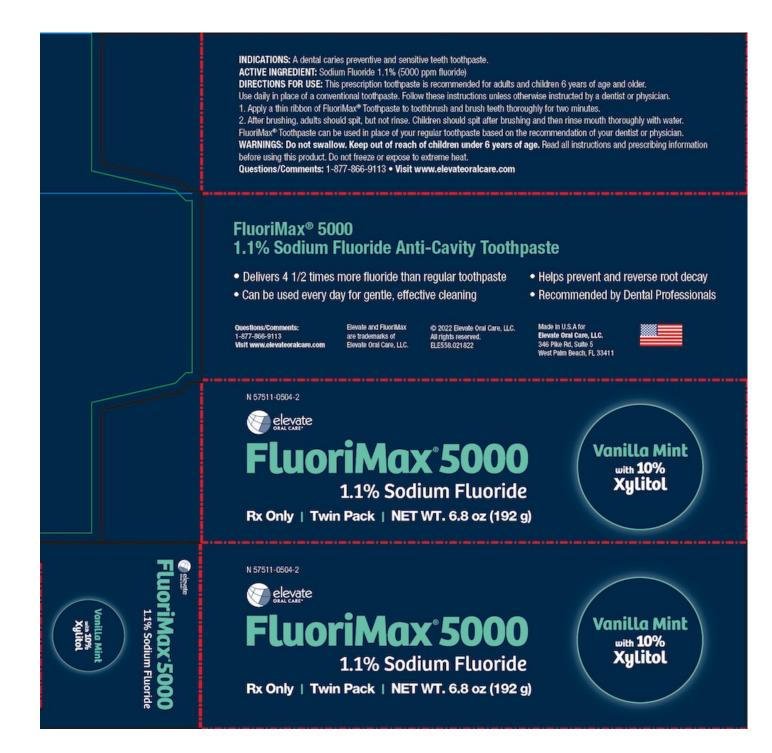
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

FluoriMax 5000 1.1% Sodium Fluorida 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



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: Y6O7T4G8P9)			

Product Characteristics			
Color	white	Score	
Shape	ROUND	Size	
Flavor	MINT	Imprint Code	
Contains			

P	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)		

Revised: 3/2022 Elevate Oral Care