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.

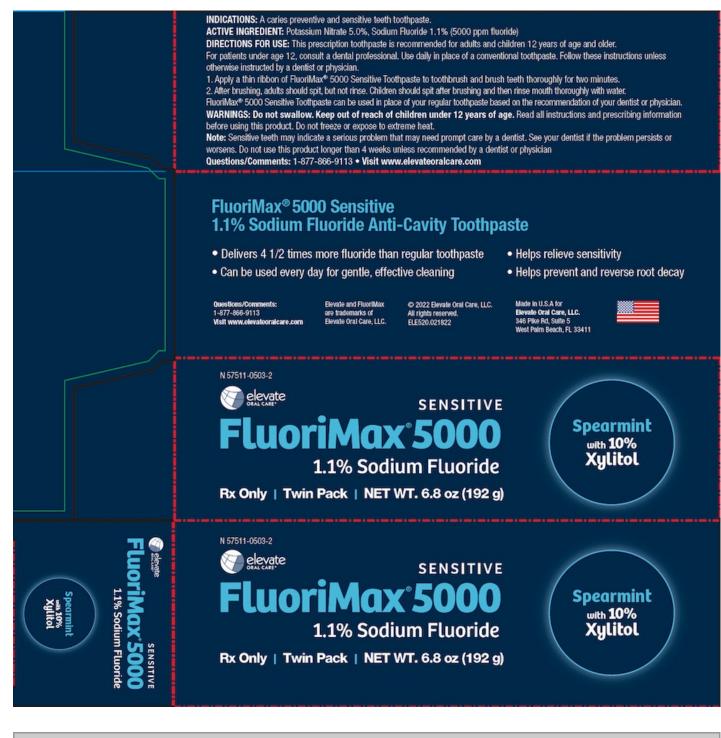
FluoriMax 5000 1.1% Sodium Fluoride & 5% Potassium Nitrate Toothpaste Spearmint

Warnings

WARNINGS: Do not swallow. Keep out of reach of children under 12 yeaars of age. Read all instructions and prescribing information before using this product. Don't 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.

Package Label and Instructions for use



FLUORIMAX 5000 SENSITIVE

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

Item Code (Source)	NDC:57511-0503

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	1.1 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				

P	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- 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)	

Revised: 3/2022 Elevate Oral Care