

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

Warnings

Do not swallow. Keep out of reach of children under 6 years of age. Read instructions and prescribing information before using product.

Label and instruction 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:Q80VPU408O)	SODIUM FLUORIDE	1.1 g in 100 g
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:57511-0504-1	96 g in 1 TUBE; Type 0: Not a Combination Product	09/01/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		09/01/2020		

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: 9/2020

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