

**FLUORIMAX 5000 SENSITIVE- 1.1% sodium fluoride with 5% potassium nitrate toothpaste paste, dentifrice**  
**Elevate Oral Care**

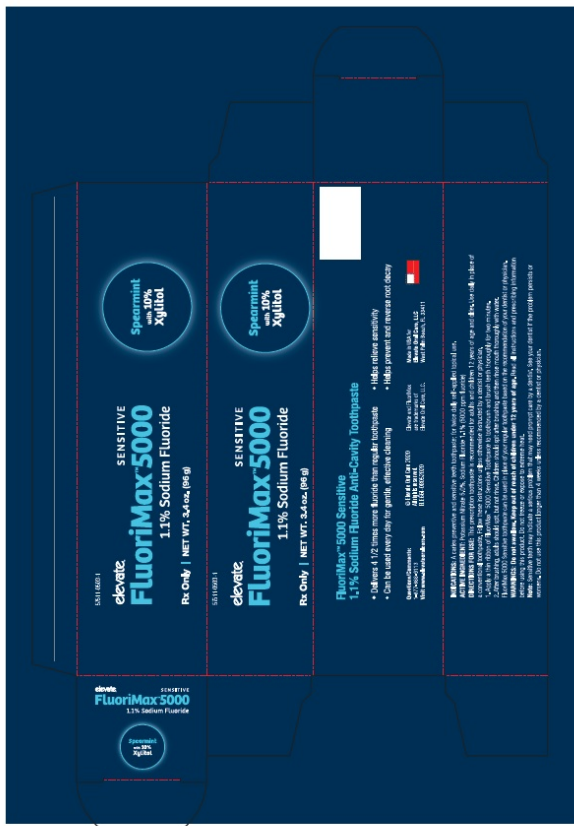
*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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

**Warnings Section**

Do not swallow. Keep out of reach of children under 12 years of age. Read all the instructions and prescribing information before using this product. Do not freeze or expose to extreme heat

**Package label and instructions for use**



**FLUORIMAX 5000 SENSITIVE**

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

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:57511-0503
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	1.1 g in 100 g

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>	ROUND	<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:57511-0503-1	96 g in 1 TUBE; Type 0: Not a Combination Product	08/31/2020	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved drug other		08/31/2020	

**Labeler** - Elevate Oral Care (002863526)

Revised: 8/2020

Elevate Oral Care