

**JUST RIGHT 5000- 1.1% sodium fluoride toothpaste gel, dentifrice  
Elevate Oral Care**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Just Right 5000 - Bubble Mint**

**OTC - ACTIVE INGREDIENT SECTION**

Sodium Fluoride 1.1% Anticavity toothpaste

**INDICATIONS & USAGE SECTION**

helps protect against cavities

**WARNINGS SECTION**

Keep out of reach of children under 6 years of age: if more than used for brushing is accidentally swallowed, get medical help or contact a poison control center right away.

*OTC - KEEP OUT OF REACH OF CHILDREN SECTION*

Keep out of reach of children under 6 years of age:

**INSTRUCTIONS FOR USE SECTION**

Directions: \*adults and children 2 years and older: wet a toothbrush and pump once to apply a pea-sized (~0.25 gram) amount of toothpaste onto a toothbrush \* brush thoroughly after meals or at least twice a day or use as directed by a dentist or physician. \* to minimize swallowing, only pump once to dispense a pea-sized amount for children under 6 years. \* supervise children's brushing until good habits are established. \* children under 2 years: ask dentist or physician.

**INACTIVE INGREDIENT SECTION**

Inactive ingredients; Sorbitol, Water, Glycerin, Hydrated silica, PEG-8, Bubble Gum/Mint Flavor, Sodium Lauryl Sulfate, Xanthan Gum, Potassium Phosphate, Sodium Benzoate, Sodium Saccharin, Mica, Blue 1.1% Solution

**OTC - QUESTIONS SECTION**

Questions? 1-877-866-9113 or visit our website at [www.elevateoralcare.com](http://www.elevateoralcare.com)

**OTC - PURPOSE SECTION**

Helps protect against Cavities

**DOSAGE & ADMINISTRATION SECTION**

Directions: \*adults and children 2 years and older: wet a toothbrush and pump once to apply a pea-sized (~0.25 gram) amount of toothpaste onto a toothbrush \* brush thoroughly after meals or at least twice a day or use as directed by a dentist or physician. \* to minimize swallowing, only pump once to dispense a pea-sized amount for children under 6 years. \* supervise children's brushing until good habits are established. \* children under 2 years: ask dentist or physician.

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

5571-1-01209  
**Just Right 5000**  
 1.1% Sodium Fluoride

**6 MONTH  
 METERED  
 DOSE  
 SYSTEM**
**Rx Only**
**NET WT  
 3.2 oz  
 (91 g)**
**INDICATIONS:** Topical fluoride for use in the prevention of dental caries.

**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 one pump (0.25 g) of Just Right™

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.

Just Right 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.

 Elevate Oral Care, West Palm Beach, FL 33411.  
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## JUST RIGHT 5000

1.1% sodium fluoride toothpaste gel, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57511-0120
<b>Route of Administration</b>	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

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	

GLYCERIN (UNII: PDC6A3C0OX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SACCHARIN (UNII: FST467XS7D)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	
<b>Shape</b>	ROUND	<b>Size</b>	
<b>Flavor</b>	BUBBLE GUM (and Mint)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57511-0120-8	91 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/01/2018	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Elevate Oral Care		002863526	manufacture(57511-0120)