

**JUST RIGHT- 0.243% 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 0.243% NaF Dentifrice**

**OTC - ACTIVE INGREDIENT SECTION**

Sodium Fluoride 0.243% (0.15% w/v fluoride ion) Anticavity

**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 (~0.35 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, FD&C Red 40, sodium lauryl sulfate, potassium phosphate monobasic, xanthan gum, flavor, sodium saccharin, sodium benzoate, mica

**OTC - QUESTIONS SECTION**

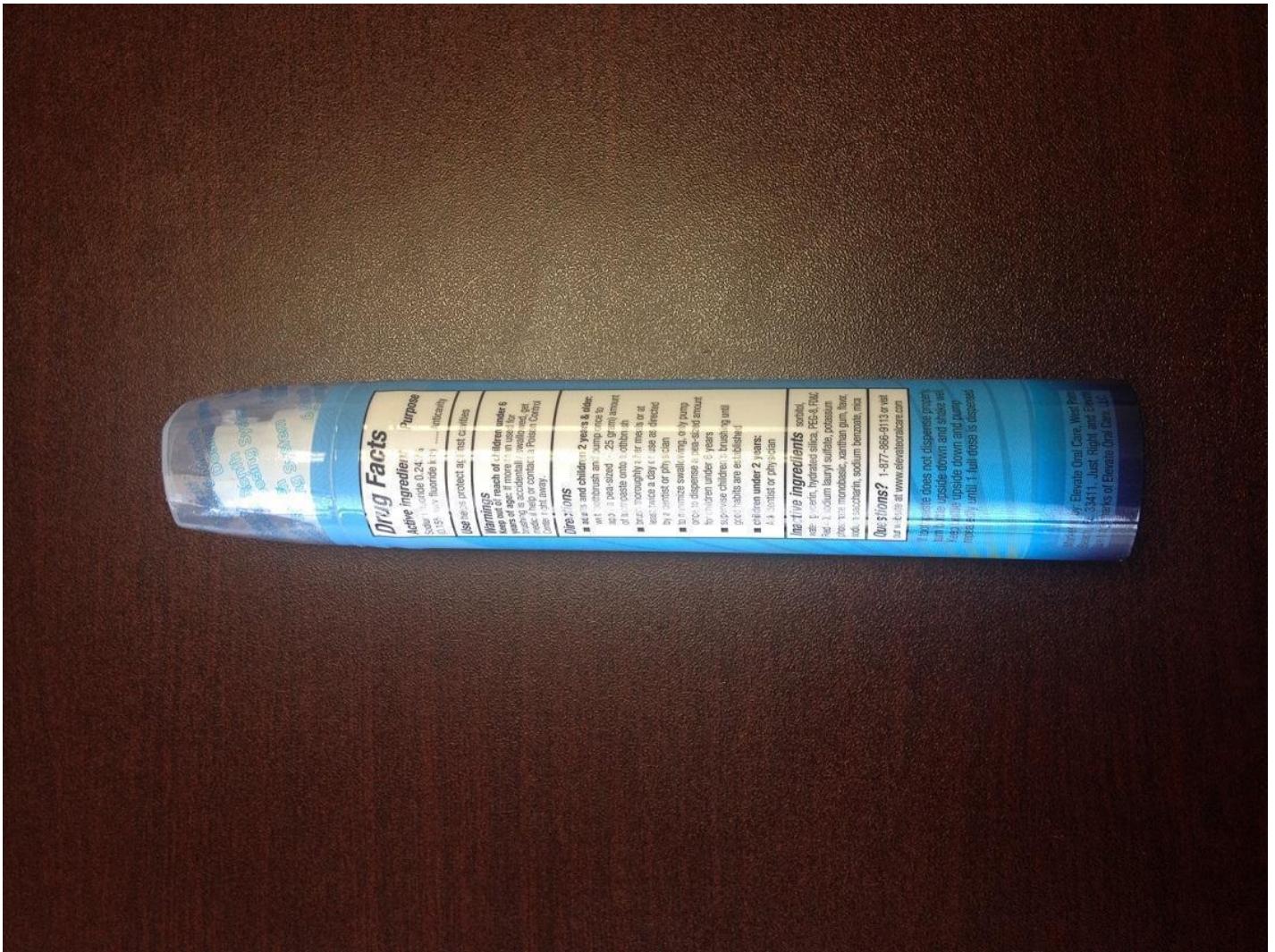
Questions? 1-877-866-9113 or visit our website at [www.elevateoralcare.com](http://www.elevateoralcare.com)

**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 (~0.35 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**

Just Right Fluoride Toothpaste Cavity Protection. 6 month dosing system. Berry Blast. Net Wt 3.3oz



(93.3g)

## JUST RIGHT

0.243% sodium fluoride toothpaste gel, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57511-0124
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.243 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SACCHARIN (UNII: FST467XS7D)	

POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)

XANTHAN GUM (UNII: TTV12P4NEE)

### Product Characteristics

Color	red	Score	
Shape	ROUND	Size	
Flavor	BERRY	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57511-0124-1	93.3 g in 1 TUBE; Type 0: Not a Combination Product	05/07/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/07/2013	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Elevate Oral Care		002863526	manufacture(57511-0124)

Revised: 1/2019

Elevate Oral Care