

JUST RIGHT 5000- 1.1% sodium fluoride toothpaste gel, 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.

Just Right 5000 Candy Apple

Warning

WARNINGS: Prolonged daily ingestion may result in various degrees of dental fluorosis in pediatric patients under age 6 years, especially if the water fluoridation exceeds 0.7 ppm, since younger pediatric patients frequently cannot perform the brushing process without significant swallowing. Use in pediatric patients under age 6 requires special supervision to prevent repeated swallowing of dentifrice which could cause dental fluorosis. Read directions carefully before using. Keep out of reach of infants and children.

PRECAUTIONS:

General: Not for systemic treatment. Do not swallow.

Pregnancy: Teratogenic Effects: Pregnancy Category B. There are no adequate and well-controlled studies in pregnant women. However, epidemiological studies conducted in areas with high levels of naturally fluoridated water showed no increase in birth defects. Heavy exposure to fluoride during in utero development may result in skeletal fluorosis which becomes evident in childhood.

Nursing Mothers: It is not known if fluoride is excreted in human milk. However, many drugs are excreted in milk, and caution should be exercised when products containing fluoride are administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients below the age of 6 years have not been established.

OVERDOSAGE: If less than 5 mg fluoride/kg body weight (i.e., less than 2.3 mg fluoride/lb body weight) have been ingested, give calcium (e.g., milk) orally to relieve gastrointestinal symptoms and observe for a few hours. If more than 5mg fluoride/kg body weight (i.e., more than 2.3 mg fluoride/lb body weight) have been ingested, give calcium (e.g., milk) orally to relieve gastrointestinal symptoms and immediately seek medical assistance. A pea-sized dose (0.25g) of JustRight 5000 toothpaste contains approximately 1.24 mg fluoride.

Directions Instructions for use

JustRight® 5000 1.1% Sodium Fluoride Prescription Toothpaste

DESCRIPTION: Self-applied topical dentifrice containing 1.1% (w/w) sodium fluoride for use in the prevention of caries.

ACTIVE INGREDIENT: Sodium Fluoride (NaF) 1.1% (w/w).

INACTIVE INGREDIENTS: Sorbitol, Water, Xylitol, Glycerin, Hydrated silica, PEG-8, Flavorings, Sodium Lauryl Sulfate, Xanthan Gum, Potassium Phosphate, Sodium Benzoate, Sodium Saccharin, Mica, FD&C Red No 40

CLINICAL PHARMACOLOGY: Frequent topical applications to the teeth of preparations having a relatively high fluoride content increase tooth resistance to acid dissolution and enhances penetration of the fluoride ion into tooth enamel.

INDICATIONS AND USAGE: A caries preventive for once daily self-applied topical use. It is well established that 1.1% sodium fluoride is safe and effective as a caries preventive when applied frequently with mouthpiece applicators. Use once daily in place of your regular toothpaste unless otherwise instructed by your dental professional.

CONTRAINDICATIONS: Do not use in pediatric patients under age 6 years unless recommended by a dentist or physician.

WARNINGS: Prolonged daily ingestion may result in various degrees of dental fluorosis in pediatric patients under age 6 years, especially if the water fluoridation exceeds 0.7 ppm, since younger pediatric patients frequently cannot perform the brushing process without significant swallowing. Use in pediatric patients under age 6 requires special supervision to prevent repeated swallowing of dentifrice which could cause dental fluorosis. Read directions carefully before using. Keep out of reach of infants and children.

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DOSAGE AND ADMINISTRATION: 1. Adults and pediatric patients 6 years of age or older, apply one pump of JustRight 5000 toothpaste to a toothbrush. Brush thoroughly once daily for two minutes, preferably at bedtime. 2. After use, adults spit, do not eat, drink, or rinse for 30 minutes. Pediatric patients, age 6-16, spit after use and rinse mouth thoroughly.

HOW SUPPLIED: 3.4 oz. (97 g) net wt. tube

NDC 57511-0002-1

STORAGE: Store at Controlled Room Temperature, 23° ± 2°C.

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Package label and instruction for use



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. For best use, store upright standing on its cap.

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.

Questions/Comments:

1-877-866-9113

Visit www.elevateoralcare.com

Just Right 5000
1.1% Sodium Fluoride



- 6 month metered dosing system
- Delivers 4 1/2 times more fluoride per brushing than regular toothpaste
- Recommended by Dental Professionals



Manufactured for Elevate Oral Care, LLC in the U.S.A with imported pump
346 Pike Rd, Suite 5
West Palm Beach, FL 33411

Questions/Comments:
1-877-866-9113
www.elevateoralcare.com

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ELE653.011724

NDC 57511-0002-1

Just Right 5000
1.1% Sodium Fluoride

6 Month Metered Dose System



With 10% Xylitol

Rx Only

Net Wt.
3.4 oz (97 g)

NDC 57511-0002-1

Just Right 5000
1.1% Sodium Fluoride

6 Month Metered Dose System



With 10% Xylitol

Rx Only

Net Wt.
3.4 oz (97 g)

JUST RIGHT 5000

1.1% sodium fluoride toothpaste gel, dentifrice

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:57511-0002 |
| 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 | red | Score | |
| Shape | ROUND | Size | |
| Flavor | APPLE (Candy Apple) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:57511-0002-1 | 97 g in 1 TUBE; Type 0: Not a Combination Product | 08/28/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug other | | 08/28/2020 | |

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

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|-------------------------|
| Elevate Oral Care | | 002863526 | manufacture(57511-0002) |

Revised: 9/2025

Elevate Oral Care