

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

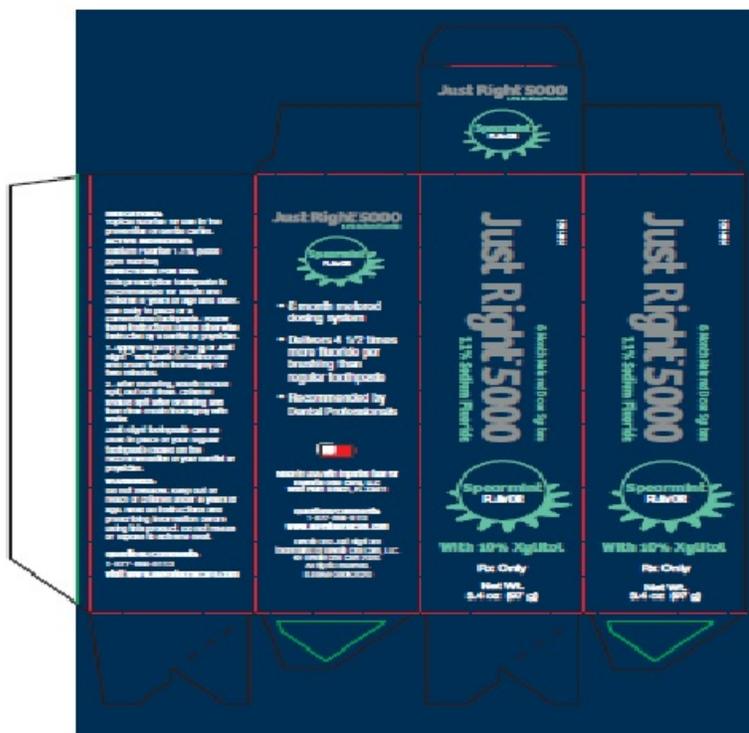
*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

### Just Right 5000 Spearmint

#### 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.

#### Package label and instruction for use



Doc: BRSP 8.3.8-02 Rev'd Approval: Pre-Prod Op. Mgr: BR-4-1-18

## JUST RIGHT 5000

1.1% sodium fluoride toothpaste gel, dentifrice

### Product Information

|                         |                         |                    |                |
|-------------------------|-------------------------|--------------------|----------------|
| Product Type            | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:57511-0003 |
| 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       |                    |
| <b>Inactive Ingredients</b>   |  |   |                      |                    |
| Ingredient Name   |  | Strength  |                      |                    |
| WATER (UNII: 059QF0K00R)  |  |   |                      |                    |
| <b>Product Characteristics</b>                                      |  |   |                      |                    |
| Color   | green                                    | Score   |                      |                    |
| Shape   | ROUND                                    | Size  |                      |                    |
| Flavor  | SPEARMINT                                | Imprint Code                                      |                      |                    |
| Contains  |  |   |                      |                    |
| <b>Packaging</b>  |  |   |                      |                    |
| #   | Item Code                                | Package Description                               | Marketing Start Date | Marketing End Date |
| 1   | NDC:57511-0003-1                         | 97 g in 1 TUBE; Type 0: Not a Combination Product | 08/28/2020           |                    |
| <b>Marketing Information</b>  |  |   |                      |                    |
| 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(57511-0003) |

Revised: 2/2021

Elevate Oral Care