

# ALLDAY 5000- 1.1% sodium fluoride 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.*

## Allday 5000 1.1% Sodium Fluoride Toothpaste, Spearmint

### WARNINGS

**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 toothpaste containing 1.1% sodium fluoride, which could cause dental fluorosis. Read directions carefully before using. Keep out of reach of infants and children.

### Instructions for Use

#### Allday® 5000 - 1.1% Sodium Fluoride Prescription Toothpaste

**DESCRIPTION:** A prescription-strength, topical fluoride toothpaste specially formulated to not irritate.

**ACTIVE INGREDIENT:** Sodium Fluoride (5000 ppm fluoride) 1.1% (w/w).

**INACTIVE INGREDIENTS:** Xylitol, Water, Hydrated Silica, Glycerin, PEG-8, Glycolipids, Xanthan Gum, Flavor, Carbomer, Sodium Hydroxide, Titanium Dioxide, Sucralose

**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:** For daily use as a dental caries preventive in adults and pediatric patients 6 years of age and older. It is well established that 1.1% sodium fluoride is safe and effective as a caries preventive when applied frequently with mouthpiece applicators. Allday 5000 can be used in place of your regular toothpaste based on the recommendation of your dentist or physician.

**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 toothpaste containing 1.1% sodium fluoride, 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. Keep out of reach of children under 6 years of age.

**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 Allday 5000 toothpaste contains approximately 1.24 mg fluoride.

**DOSAGE AND ADMINISTRATION:** 1. Adults and pediatric patients 6 years of age or older, apply a thin ribbon of Allday® 5000 Anticavity Toothpaste to a toothbrush. Brush thoroughly for two minutes. 2. After brushing, adults should spit, but not rinse. For best results, do not eat, drink, or rinse for 30 minutes. Pediatric patients, age 6-16, should spit after brushing and rinse mouth thoroughly with water. Allday 5000 can be used in place of your regular toothpaste based on the recommendation of your dentist or physician.

#### HOW SUPPLIED:

Two 3.4 oz. (96g) net wt. tube

N 57511-0005-1

**STORAGE:** Store at room temperature, 23°C ± 2°C.

# Primary Label Principal Display Label

**DESCRIPTION:** A prescription strength, topical fluoride toothpaste specially formulated to resist decay.  
**ACTIVE INGREDIENT:** Sodium Fluoride 1.1% (500 ppm Fluoride)

**INDICATIONS AND USAGE:** For daily use as a dental care preventive in adults and pediatric patients 5 years of age and older.

**WARNING:** Not for systemic use. **DO NOT SWALLOW.** Keep out of reach of children under 6 years of age.

**DOSSAGE AND ADMINISTRATION:** Follow these instructions unless otherwise directed by your dental professional.  
 1. Adults and pediatric patients 5 years of age or older, apply a thin ribbon of Allday® 5000 Anticavity Toothpaste to a toothbrush. Brush thoroughly for two minutes.  
 2. After brushing, rub the toothpaste on the tongue. For best results, do not eat, drink, or rinse for 30 minutes.  
 For pediatric patients ages 6-16 years, dispense after brushing and then use mouth spray thoroughly with water.  
 Allday 5000 can be used in place of your regular toothpaste based on the recommendations of your dentist or physician.

**STORAGE:** Store at room temperature, 20°C to 25°C.  
 Before using this product, see inside for complete product information.

Allday is a registered trademark of Florida Oral Care, LLC.  
 © 2014 Florida Oral Care All rights reserved.  
 813721-0005

Manufactured by Florida Oral Care, LLC 11010th HALL, 1101 Pkwy, Suite 9 West Palm Beach, FL 33411

Questions/Comments? 1-877-654-9113 [www.floridoralcare.com](http://www.floridoralcare.com)

**Allday 5000**  
 SLS and CAPB Free  
**ANTICAVITY Toothpaste | Rx Only**

- Next generation foaming agent soothes and refreshes
- Ideal for dry mouth or anyone prone to irritated gums
- Over 4 1/2 times more fluoride than regular toothpaste

For help relieving dry mouth symptoms all day long, ask your dental professional about Allday® Dry Mouth Spray and Allday Dry Mouth Gel.

**Allday 5000**  
 SLS and CAPB Free  
**ANTICAVITY Toothpaste | Rx Only**  
 1.1% SODIUM FLUORIDE | Twin Pack | NET WT. 4.8 oz. (192 g)

**Mild Mint 44% Xylitol**

**Allday 5000**  
 SLS and CAPB Free  
**ANTICAVITY Toothpaste | Rx Only**  
 1.1% SODIUM FLUORIDE | Twin Pack | NET WT. 4.8 oz. (192 g)

**Mild Mint 44% Xylitol**

## ALLDAY 5000

1.1% sodium fluoride toothpaste paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:57511-0005
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	1.1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	

<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>DIMETHICONE PEG-8 ADIPATE</b> (UNII: 09Y0SJ39VP)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white (white paste)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57511-0005-1	2 in 1 BOX	05/31/2022	
1		1 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/31/2022	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Elevate Oral Care		002863526	manufacture(57511-0005)