

## **ALLDAY 5000 SENSITIVE- 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](#).*

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### **Allday 5000 Sensitive**

#### **Warnings**

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**WARNINGS:** Prolonged daily ingestion may result in various degrees of dental fluorosis in pediatric patients under age 12 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 12 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 12 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 12 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.

#### **Instructions for Use**



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

**DESCRIPTION:** A prescription-strength, topical fluoride toothpaste specially formulated to not irritate, for the use in the prevention of caries and for sensitive teeth.

**ACTIVE INGREDIENT:** Potassium Nitrate 5.0% 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, Bitter Masking Agent

**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 12 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 Sensitive 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 12 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 12 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 12 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.

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**DOSAGE AND ADMINISTRATION:** 1. Adults and pediatric patients 12 years of age or older, apply a thin ribbon of Allday® 5000 Sensitive 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 12-16, should spit after brushing and rinse mouth thoroughly with water. Allday 5000 Sensitive 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 57511-0006-1

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

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INDICATIONS: A prescription-strength, topical fluoride toothpaste specially formulated not to irritate, for use in the prevention of caries and for sensitive teeth.

ACTIVE INGREDIENT: Potassium Nitrate 5.0%, Sodium Fluoride 1.1% (5000 ppm fluoride)

INDICATIONS AND USAGE: For daily use as a dental caries preventive in adults and pediatric patients 12 years of age and older.

WARNINGS: Not for systemic treatment. DO NOT SWALLOW. Keep out of reach of children under 12 years of age.

DOSAGE AND ADMINISTRATION: Follow these instructions unless otherwise directed by your dental professional: For patients under age 12, consult a dental professional.

1. Adults and pediatric patients 12 years of age and older, apply a thin ribbon of Allday® 5000 Sensitive 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, ages 12-16 years, should spit after brushing and then rinse mouth thoroughly with water.

Allday® 5000 Sensitive Anticavity 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 12 years of age. Read all instructions and prescribing information before using this product. Do not freeze or expose to extreme heat.

Note: Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or physician.

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

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



Questions/Comments?  
1-877-866-9113  
[www.elevateoralcare.com](http://www.elevateoralcare.com)

# SENSITIVE Allday® 5000

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
- Helps prevent and treat dental hypersensitivity

†Better foaming and less irritating on gum tissue than sodium lauryl sulfate (SLS) or cocamidopropyl betaine (CAPB). Data on file.



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



# SENSITIVE Allday® 5000

ANTICAVITY Toothpaste | Rx Only

1.1% SODIUM FLUORIDE | Twin Pack | NET WT. 6.8 oz. (192 g)

NDC 57511-0006-1

SLS and CAPB Free

Mild Mint  
38%  
Xylitol



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SLS and CAPB Free

Mild Mint  
38%  
Xylitol

**ALLDAY 5000 SENSITIVE**

1.1% sodium fluoride toothpaste paste, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:57511-0006
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>POTASSIUM NITRATE</b> (UNII: RU45X2JNOZ) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	1.1 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>MINT</b> (UNII: FV98Z8GITP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: HHT01ZNK31)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<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:57511-0006-1	2 in 1 BOX	11/14/2025	

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		11/12/2025	

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

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

Establishment			
Name	Address	ID/FEI	Business Operations
Elevate Oral Care		002863526	manufacture(57511-0006)

Revised: 11/2025

Elevate Oral Care