

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

Instructions for Use

Allday™ 5000 - 1.1% Sodium Fluoride Prescription Toothpaste

DESCRIPTION: A prescription-strength, topical fluoride toothpaste specially formulated for dry mouth sufferers.

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 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:

3.4 oz. (96g) net wt. tube

N 57511-0005-1

STORAGE: Store at Controlled Room Temperature, 20-25 degrees C (68-77 degrees F).

Package Label

Allday™ 5000

DRY MOUTH Toothpaste | Rx Only

Specially formulated for dry mouth

- Maximum strength xylitol
- Over 4 1/2 times more fluoride*
- Non-acidic formula
- SLS and CAPB Free†

* Than regular toothpaste. † This product does not contain sodium lauryl sulfate (SLS) or cocamidopropyl betaine (CAPB).



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

N 57511-0005-1

Allday™ 5000

DRY MOUTH Toothpaste | Rx Only

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

Mild Mint
44%
Xylitol

N 57511-0005-1

Allday™ 5000

DRY MOUTH Toothpaste | Rx Only

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

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WARNINGS: Not for systemic treatment. DO NOT SWALLOW. Keep out of reach of children under 6 years of age.

DOSAGE AND ADMINISTRATION: Follow these instructions unless otherwise directed by your dental professional:

1. Adults and pediatric patients 6 years of age or older, apply a thin ribbon of Allday® 5000 Dry Mouth 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 6-16 years, should spit after brushing and then 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.

STORAGE: Store at controlled room temperature, 68-77°F (20-25°C)

Before using this product, see inside for complete product information.

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ELE736.030222

Manufactured in the U.S.A.
for: Elevate Oral Care, LLC
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West Palm Beach, FL 33411



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

ALLDAY 5000

1.1% sodium fluoride toothpaste paste, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:57511-0005
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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
DIMETHICONE PEG-8 ADIPATE (UNII: 09Y0SJ39VP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (white paste)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

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
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Elevate Oral Care		002863526	manufacture(57511-0005)
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Revised: 2/2024

Elevate Oral Care