**SODIUM FLUORIDE 5000 PPM- sodium fluoride paste**
**Westminster Pharmaceuticals, LLC**

*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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**SODIUM FLUORIDE 5000 ppm**

Rx Only

***1.1% Sodium fluoride***
*Prescription Strength Toothpaste*

## DESCRIPTION

Self-topical neutral fluoride dentifrice containing 1.1% (w/w) sodium fluoride for use as a dental caries preventive in adults and pediatric patients.

### Active Ingredient

Sodium Fluoride 1.1% (w/w)

### Inactive Ingredients

Dicalcium phosphate, flavor, glycerin, hydrated silica, purified water, sodium benzoate, sodium lauryl sulfate, sorbitol, titanium dioxide, xanthan gum, xylitol. This product also contains flavor, FD&C blue No. 1 (Spearmint only), FD&C red No. 40 (Fruity only).

## CLINICAL PHARMACOLOGY

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

## INDICATIONS AND USAGE

A dental caries preventive; for once daily self-applied topical use. It is well established that 1.1% sodium fluoride is safe and extraordinarily effective as a caries preventive when applied frequently with mouthpiece applicators.[1-4] Sodium Fluoride 5000 ppm 1.1% sodium fluoride in a squeeze-tube is easily applied onto a toothbrush. This prescription should be used once daily in place of your regular toothpaste, unless otherwise instructed by your dental professional. May be used in areas where drinking water is fluoridated since topical fluoride cannot produce fluorosis. (See WARNINGS for exception.)

## 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 0.6 ppm, since younger pediatric patients frequently cannot perform the brushing process without significant swallowing. Use in pediatric patients under age 6 years requires special supervision to prevent repeated swallowing of toothpaste, which could cause dental fluorosis. Pediatric patients under age 12 should be supervised in the use of this product. Read directions carefully before using.

**Keep out of reach of infants and children.**

## PRECAUTIONS

### General

Not for systemic treatment. **DO NOT SWALLOW.**

### Carcinogenesis, Mutagenesis, Impairment of Fertility

In a study conducted in rodents, no carcinogenesis was found in male and female mice and female rats treated with fluoride at dose levels ranging from 4.1 to 9.1 mg/kg of body weight. Equivocal evidence of carcinogenesis was reported in male rats treated with 2.5 and 4.1 mg/kg of body weight.

In a second study, no carcinogenesis was observed in rats, males or females, treated with fluoride up to 11.3 mg/kg of body weight. Epidemiological data provide no credible evidence for an association between fluoride, either naturally occurring or added to drinking water, and risk of human cancer. Fluoride ion is not mutagenic in standard bacterial systems. It has been shown that fluoride ion has potential to induce chromosome aberrations in cultured human and rodent cells at doses much higher than those to which humans are exposed. *In vivo* data are conflicting. Some studies report chromosome damage in rodents, while other studies using similar protocols report negative results.

Potential adverse reproductive effects of fluoride exposure in humans have not been adequately evaluated. Adverse effects on reproduction were reported for rats, mice, fox, and cattle exposed to 100 ppm or greater concentrations of fluoride in their diet or drinking water. Other studies conducted in rats demonstrated that lower concentrations of fluoride (5 mg/kg of body weight) did not result in impaired fertility and reproductive capabilities.

### Pregnancy

Teratogenic Effects

*Pregnancy Category B*

It has been shown that fluoride crosses the placenta of rats, but only 0.01% of the amount administered is incorporated in fetal tissue. Animal studies (rats, mice, rabbits)

have shown that fluoride is not a teratogen. Maternal exposure to 12.2 mg fluoride/kg of body weight (rats) or 13.1 mg/kg of body weight (rabbits) did not affect the litter size or fetal weight and did not increase the frequency of skeletal or visceral malformations. 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. Reduced milk production was reported in farm-raised fox when the animals were fed a diet containing a high concentration of fluoride (98-137 mg/kg of body weight). No adverse effects on parturition, lactation, or offspring were seen in rats administered fluoride up to 5 mg/kg of body weight.

### Pediatric Use

The use of Sodium Fluoride 5000 ppm in pediatric age groups 6 to 16 years as a caries preventive is supported by pioneering clinical studies with 1.1% sodium fluoride gels in mouth trays in students age 11-14 years conducted by Englander et al.[2-4] Safety and effectiveness in pediatric patients below the age of 6 years have not been established. Please refer to the CONTRAINDICATIONS and WARNINGS sections.

## ADVERSE REACTIONS

Allergic reactions and other idiosyncrasies have been rarely reported.

To report SUSPECTED ADVERSE REACTIONS, contact Westminster Pharmaceuticals, LLC at 1-844-221-7294 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

## OVERDOSAGE

Accidental ingestion of large amounts of fluoride may result in acute burning in the mouth and sore tongue. Nausea, vomiting, and diarrhea may occur soon after ingestion (within 30 minutes) and are accompanied by salivation, hematemesis, and epigastric cramping abdominal pain. These symptoms may persist for 24 hours. If less than 5 mg fluoride/kg body weight (i.e., less than 2.3 mg fluoride/lb body weight) has been ingested, give calcium (e.g., milk) orally to relieve gastrointestinal symptoms and observe for a few hours. If more than 5 mg fluoride/kg body weight (i.e., more than 2.3 mg fluoride/lb body weight) have been ingested, induce vomiting, give orally soluble calcium (e.g., milk, 5% calcium gluconate or calcium lactate solution) and immediately seek medical assistance. For accidental ingestion of more than 15 mg fluoride/kg of body weight (i.e., more than 6.9 mg fluoride/lb body weight), induce vomiting and admit immediately to a hospital facility.

A treatment dose (a thin ribbon) of Sodium Fluoride 5000 ppm contains 2.5 mg fluoride. A 3.4 FL OZ tube (100 mL) contains approximately 605 mg fluoride.

## DOSAGE AND ADMINISTRATION

Follow these instructions unless otherwise instructed by your dental professional:

1. Adults and pediatric patients 6 years of age or older, apply a thin ribbon of Sodium Fluoride 5000 ppm to a toothbrush. Brush teeth thoroughly once daily for at least two minutes, preferably at bedtime, in place of your regular toothpaste.
2. After use, adults expectorate. For best results, do not eat, drink, or rinse for 30 minutes. Pediatric patients, age 6-16, expectorate after use and rinse mouth thoroughly.

### How Supplied

| | |
|---|---|
| 3.4 FL OZ (100mL) NET WT. Tube | NDC 69367-311-01 Spearmint |
| 3.4 FL OZ (100mL) NET WT. Tube | NDC 69367-312-01 Fruity |

## STORAGE

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

## REFERENCES


1. Accepted Dental Therapeutics, Ed. 40, ADA, Chicago. P. 405-407, 1984.
2. Englander, HR, Keyes et al:JADA 75: 638-644, 1967.
3. Englander, HR, et al:JADA 78: 783-787, 1969.
4. Englander, HR, et al:JADA 83: 354-358, 1971.


**Manufactured for:**
Westminster Pharmaceuticals, LLC
Nashville, TN 37217
Rev. 01/23

## PRINCIPAL DISPLAY PANEL - 100 mL Tube Carton - SPEARMINT

SPEARMINT
NDC 69367-311-01
Rx Only

Sodium Fluoride 5000 ppm
1.1% Sodium Fluoride Prescription Strength Toothpaste

3.4 FL OZ (100 mL)

Westminster
Pharmaceuticals

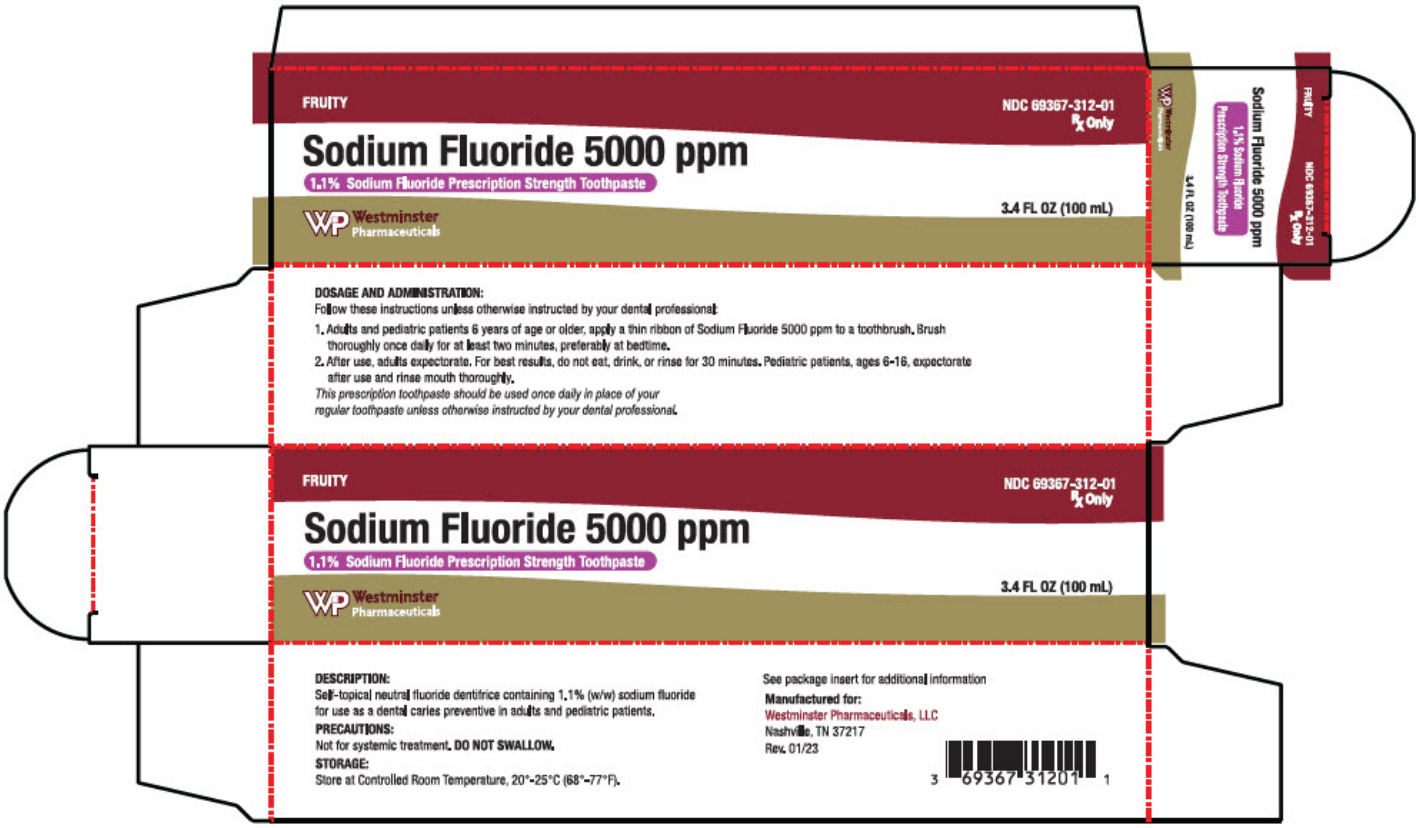

**PRINCIPAL DISPLAY PANEL - 100 mL Tube Carton - FRUITY**

FRUITY
NDC 69367-312-01
Rx Only

Sodium Fluoride 5000 ppm
1.1% Sodium Fluoride Prescription Strength Toothpaste

3.4 FL OZ (100 mL)

Westminster
Pharmaceuticals




# SODIUM FLUORIDE 5000 PPM

sodium fluoride paste

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:69367-311 |
| **Route of Administration** | DENTAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **SODIUM FLUORIDE** (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 6 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **HYDRATED SILICA** (UNII: Y6O7T4G8P9) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **DIBASIC CALCIUM PHOSPHATE DIHYDRATE** (UNII: O7TSZ97GEP) | |

| | |
|---|---|
| **XYLITOL** (UNII: VCQ006KQ1E) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | BLUE | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | SPEARMINT | **Imprint Code** | |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:69367-311-01 | 100 mL in 1 TUBE; Type 0: Not a Combination Product | 06/16/2021 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| UNAPPROVED DRUG OTHER | | 06/16/2021 | |

# SODIUM FLUORIDE 5000 PPM

sodium fluoride paste

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| Active Ingredient/Active Moiety | | |
|---|---|---|
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| **SODIUM FLUORIDE** (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 6 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **HYDRATED SILICA** (UNII: Y6O7T4G8P9) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |

| | |
|---|---|
| **DIBASIC CALCIUM PHOSPHATE DIHYDRATE** (UNII: O7TSZ97GEP) | |
| **XYLITOL** (UNII: VCQ006KQ1E) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | PINK | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | FRUIT | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:69367-312-01 | 100 mL in 1 TUBE; Type 0: Not a Combination Product | 06/16/2021 | |

## Marketing Information

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|---|---|---|---|
| UNAPPROVED DRUG OTHER | | 06/16/2021 | |

## Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 10/2024 Westminster Pharmaceuticals, LLC