SODIUM FLUORIDE AND POTASSIUM NITRATE- sodium fluoride and potassium nitrate gel
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.

Sodium Fluoride 1.1% and Potassium Nitrate 5% Sensitive

Rx Only

1.1% Sodium fluoride, 5% Potassium Nitrate

Prescription Strength Toothpaste for Sensitive Teeth

DESCRIPTION

Self-topical neutral fluoride toothpaste containing 1.1% (w/w) sodium fluoride and 5% potassium nitrate.

Active Ingredients

Sodium Fluoride 1.1% (w/w)

Potassium Nitrate 5%

Inactive Ingredients

D&C Yellow No.10, Dicalcium Phosphate, FD&C Blue No.1, Glycerin, Hydrated Silica, Mint Flavor, Purified Water, Sodium Benzoate, Sodium Luaryl Sulfate, Sodium Saccharin, Sorbitol, Titanium Dioxide, Xanthum Gum.

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 and sensitive teeth toothpaste; for twice daily self-applied topical use, followed by rinsing. Helps reduce the painful sensitivity of the teeth to cold, heat, acid, sweets or contact in adult patients and children 12 years of age and older. 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 1.1% and Potassium Nitrate 5% Sensitive in a squeeze-tube is easily applied onto a toothbrush. This prescription toothpaste should be used twice daily in place of your regular toothpaste, unless otherwise instructed by your dental professional. May be used whether or not drinking water is fluoridated, since topical fluoride cannot produce fluorosis. (See WARNINGS for exception.)

CONTRAINDICATIONS

Do not use in pediatric patients under age 12 years unless recommended by a dentist or physician.

WARNINGS

Not for systemic treatment - DO NOT SWALLOW. Keep out of the reach of children. Children under 12 years of age, consult a dentist or physician.

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.

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 has 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

Safety and effectiveness in pediatric patients below the age of 12 years have not been established. Please refer to the CONTRAINDICATIONS and WARNINGS sections.

Geriatric Use

No studies of Sodium Fluoride 1.1% and Potassium Nitrate 5% Sensitive have been conducted to determine whether subjects aged 65 and over respond differently from younger subjects.

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, vomitting, 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) have 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 vomitting, 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 vomitting and admit immediately to a hospital facility.

A treatment dose (a thin ribbon) of Sodium Fluoride 1.1% and Potassium Nitrate 5%

Sensitive contains approximately 2.5 mg fluoride. A 3.4 FL OZ (100 mL) tube contains approximately 575 mg fluoride.

DOSAGE AND ADMINISTRATION

Follow these instructions unless otherwise instructed by your dental professional:

1. Adults and children 12 years of age or older, apply at least a 1 inch strip of Sodium Fluoride 1.1% and Potassium Nitrate 5% Sensitive onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute, expectorate, and rinse mouth thoroughly.
2. Use twice daily, (morning and evening) or as recommended by a dentist or physician. Make sure to brush all sensitive areas of the teeth. Children under 12 years of age: consult a dentist or physician.

How Supplied

3.4 FL OZ (100mL) net wt. tube	NDC 69367-318-01 Mild Mint

STORAGE

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

REFERENCES

1. American Dental Association, Accepted Dental Therapeutics, Ed. 40, Chicago, ADA, 405-407(1984).
2. H.R. Englander et al., JADA, 75, 638-644 (1967).
3. H.R. Englander et al., JADA, 78, 783-787 (1969).
4. H.R. Englander et al., JADA, 82, 354-358 (1971).

Manufactured for:
Westminster Pharmaceuticals, LLC
Nashville, TN 37217
Rev. 02/24

PRINCIPAL DISPLAY PANEL - 100 mL Tube Carton

MILD MINT

NDC 69367-318-01
Rx Only

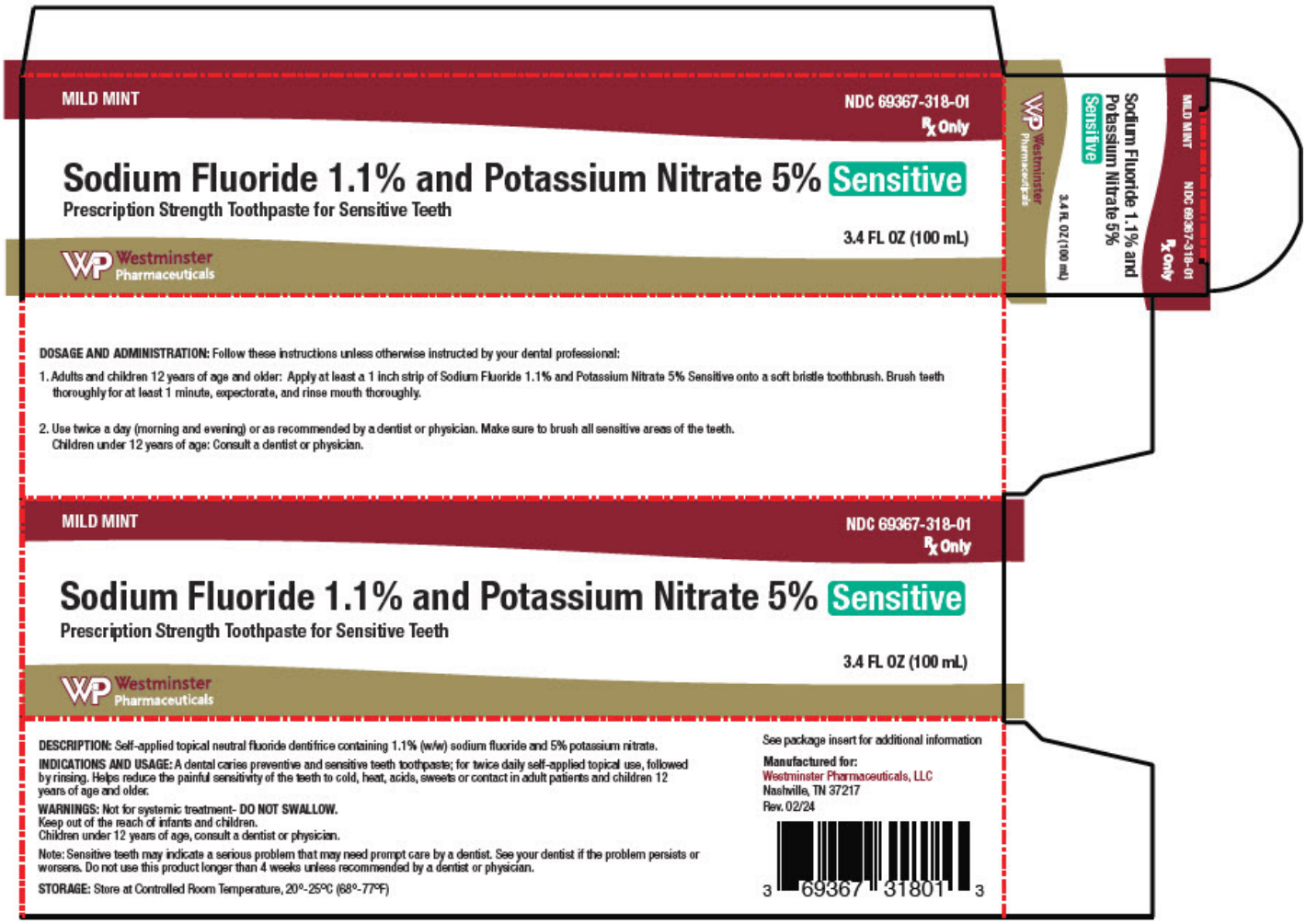
Sodium Fluoride 1.1% and Potassium Nitrate 5%

Prescription Strength Toothpaste for Sensitive Teeth

Sensitive

3.4 FL OZ (100 mL)

Westminster
Pharmaceuticals



SODIUM FLUORIDE AND POTASSIUM NITRATE

sodium fluoride and potassium nitrate gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69367-318
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	5.8 mg in 1 mL
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	57.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
SORBITOL (UNII: 506T60A25R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	GREEN	**Score**	
Shape		**Size**	
Flavor	PEPPERMINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69367-318-01	1 in 1 CARTON	06/15/2022	
1		100 mL 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		06/15/2022	

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 4/2024 Westminster Pharmaceuticals, LLC