

**SODIUM FLUORIDE 5000 PPM DRY MOUTH- sodium fluoride gel, dentifrice
Sheffield 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 5000 PPM Dry Mouth

SODIUM FLUORIDE 5000 ppm Dry Mouth

Description:

Self-topical neutral fluoride toothpaste 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:

water, sorbitol, hydrated silica, propylene glycol, glycerin, PEG-40 hydrogenated castor oil, poloxamer 407, xanthan gum, PVM/MA copolymer, flavor, cocamidopropyl betaine, sodium saccharin, dipotassium phosphate, sodium hydroxide, sodium benzoate, potassium sorbate, cetylpyridinium chloride, pectin, FD&C Blue no. 1

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 Dry Mouth brand of 1.1% sodium fluoride toothpaste in a squeeze tube is easily applied onto a toothbrush. This prescription toothpaste 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 Dry Mouth 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 to 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.

Geriatric Use

No studies of Sodium Fluoride 5000 ppm Dry Mouth 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 Sheffield Pharmaceuticals, LLC at 1-800-222-1087 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) 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 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 Dry Mouth contains 2.5 mg fluoride. A 3.4 FL OZ tube (100 mL) tube contains approximately 610 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 Dry Mouth to a toothbrush. Brush thoroughly once daily for 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, ages 6-16 years, expectorate after use and rinse mouth thoroughly.

HOW SUPPLIED

3.4 FL OZ (100 mL) tube

NDC 11527-755-34

STORAGE:

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

REFERENCES:

1. Accepted Dental Therapeutics, Ed. 40, ADA, Chicago. P. 405-407, (1984).
2. H.R. Englander, Keyes 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 83:354-358, (1971).

PRINCIPAL DISPLAY PANEL - 100 mL Tube

Wentworth NDC 11527-755-34

Sodium Fluoride 5000 ppm

SOOTHING MINT

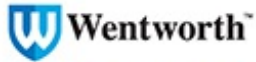
DRY MOUTH*

1.1% Sodium Fluoride, sls free formula

Prescription Strength Toothpaste for Dry Mouth

3.4 FL OZ (100 mL)

RX ONLY



NDC 11527-755-34

Sodium Fluoride 5000 ppm

DRY MOUTH*

SOOTHING MINT

**1.1% Sodium Fluoride, sls free formula
Prescription Strength Toothpaste for Dry Mouth**

3.4 FL OZ (100 mL) RX ONLY

*Formulated for Dry Mouth Sufferers

DESCRIPTION: Self-topical neutral fluoride toothpaste containing 1.1% (w/w) sodium fluoride.

INDICATIONS AND USAGE: For once-daily self-applied topical use as a dental caries preventive in adults and pediatric patients age 6 years and older.

WARNINGS: Not for systemic treatment - **DO NOT SWALLOW.**
Read directions carefully before using. Keep out of reach of infants and children.

DOSAGE AND ADMINISTRATION: (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 Dry Mouth toothpaste to a toothbrush. Brush thoroughly once daily for 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, ages 6 - 16 years, expectorate after use and rinse mouth thoroughly.

STORAGE: Store at Controlled Room Temperature, 68°-77°F (20°-25°C).
See package insert for additional information.

Manufactured by: Sheffield Pharmaceuticals
170 Broad Street, New London, CT 06320
Rev. 10/20 250684



PRINCIPAL DISPLAY PANEL - 100 mL Carton

Wentworth NDC 11527-755-34

Sodium Fluoride 5000 ppm

SOOTHING MINT

DRY MOUTH*

1.1% Sodium Fluoride, sls free formula

Prescription Strength Toothpaste for Dry Mouth

3.4 FL OZ (100 mL)

RX ONLY



SODIUM FLUORIDE 5000 PPM DRY MOUTH

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:11527-755
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	6.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
XANTHAN GUM (UNII: TTV12P4NEE)	

METHYL VINYL ETHER AND MALEIC ACID COPOLYMER (175000 WAMW) (UNII: 9F20VSM0VU)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
DIBASIC POTASSIUM PHOSPHATE (UNII: CI71S98N1Z)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
PECTIN (UNII: 89NA02M4RX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11527-755-34	1 in 1 CARTON	01/08/2021	
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		01/08/2021	

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(11527-755) , analysis(11527-755)