PRO GEL 5000 MINT- sodium fluoride gel, dentifrice
PRO GEL 5000 CITRUS- sodium fluoride gel, dentifrice
DENTAL ALLIANCE HOLDINGS 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.

Gel 5000

Description:

Self-topical neutral fluoride gel containing 1.1% sodium fluoride for use as a dental caries preventive in adults and pediatric patients.

Active Ingredient:

Sodium Fluoride, 1.1% (w/w)

Other Ingredients:

Glycerin, Hydrated Silica, Hydrogenated Starch Hydrolysate (HSH), Hydroxyapatite, Hydroxyethyl Cellulose, Natural Flavors (Mint only), Natural and Artificial Flavors (Citrus only), Polysorbate 20, Potassium Sorbate, Saccharin, Sodium Benzoate, Sodium Bicarbonate, Sodium Hydroxide, Sodium Lauryl Sulfate, Water, Xylitol

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 the tooth structure.

Indications and Use:

A dental caries preventive; for once daily self-applied topical use. It is well established that a 1.1% sodium fluoride is safe and extraordinarily effective as a caries preventive when applied frequently with mouthpiece applicators.1-4 CariFree CTx4 Gel 5000 brand of 1.1% sodium fluoride toothpaste in a squeeze tube is easily applied onto a toothbrush as well as a mouthpiece tray. This prescription dental gel should be used once daily following use of a 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 water fluoridation exceeds 0.6 ppm. Use in pediatric patients under age 6 years requires special supervision to prevent repeated swallowing of gel. Read directions carefully before using. Keep out of reach of infants and children.

Precautions:

General: Not for systemic treatments. 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 provided no credible evidence for an association between fluoride, either naturally occurring or added to drinking water, and risk of human cancer. Fluoride is not mutagenic in standard bacterial systems. It has been shows 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:

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 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. Reduce 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 CariFree CTx4 Gel 5000 in pediatric age group 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 **Contraindications** and **Warnings** sections.

Adverse Reactions:

Allergic reactions and other idiosyncrasies have been rarely reported.

Overdosage:

Accidental ingestion of large amounts of fluoride may result in acute burning in the mouth and sore tongue. Nauseau, 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 (ie, less than 2.3 mg fluoride/lb body weight) have been ingested, give calcium (eg, milk) orally to relieve gastrointestinal symptoms and observe for a few hours. If more than 5 mg fluoride/kg body weight (ie, more than 2.3 mg fluoride/lb body weight) have been ingested, induce vomiting, give orally soluble calcium (eg, 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 (ie, 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 CariFree CTx4 Gel 5000 contains 2.5 mg fluoride. A 2 oz tube contains 284 mg fluoride.

Dosage and Administration:

Follow these instructions unless otherwise instructed by your dental professional:
1. After brushing with toothpaste, adults and pediatric patients 6 years of age and older, apply a thin ribbon of gel to the teeth with a toothbrush for at least one minute, preferably at bedtime.
2. Adult patients, expectorate gel after use. For best results, do not eat, drink or rinse for 30 minutes. Pediatric patients, age 6-16, expectorate gel after use and rinse mouth thoroughly.

How Supplied:

2 oz (56.699g) tube.

NDC# 61578-205-01 (Mint)

NDC# 61578-206-01 (Citrus)

Storage:

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

References:

1. American Dental Association, Accepted Dental Therapeutics, Ed 40, Chicago (1984): 405-407.
2. HR Englander et al, “Clinical Anticaries Effect of Repeated Topical Sodium Fluoride Applications by Mouthpieces,” JADA, 75 (1967): 638-644.
3. HR Englander et al, “Residual Anticaries Effect of Repeated Topical Sodium Fluoride Applications by Mouthpieces,” JADA, 78 (1969): 783-787.
4. HR Englader et al, “Incremental Rates of Dental Caries After Repeated Topical Sodium Fluoride
Applications in Children with Lifelong Consumption of Fluoridated Water,” JADA, 82 (1971): 354-358.

PRO Gel 5000 Mint and Citrus enclosure and carton labels:


PRO GEL 5000
1.1% NEUTRAL
SODIUM FLUORIDE
ANTI-CAVITY TOOTHPASTE
CARIFREE
CARIFREE®
CARIFREE
Die Line 12-4-19
CariFree PRO Gel 5000 is for adults and children to aid in the prevention of dental caries and hypersensitivity. PRO Gel 5000 is a neutral 1.1% sodium fluoride gel containing xylitol and nanoparticle hydroxyapatite at an elevated pH to neutralize acids and promote remineralization.
Directions:
■ Use once daily as your normal dentifrice or as directed by your dental professional. Apply a thin ribbon of gel dentifrice to toothbrush and brush thoroughly on all tooth surfaces for at least one minute.
■ Adults: expectorate gel after use and for best results do not eat, drink or rinse for 30 minutes.
■ Adolescent patients, ages 6–17: expectorate after use and rinse mouth thoroughly. Instruct children under 12 to minimize swallowing. Supervise children as necessary until capable of using without supervision.
■ Children under 6 years of age: consult a dental professional.
Precautions: DO NOT SWALLOW. As with all medications, keep out of reach of infants and children. Store at controlled room temperature 20–25 degrees C (68–77 degrees F). See package insert for further information.
/CariFree
@_carifree
/carifree_
@CariFree
You Tube
/carifree
PRO GEL 5000
1.1% NEUTRAL
SODIUM FLUORIDE
ANTI-CAVITY TOOTHPASTE
Rx only
mint
pH elevated
2.4 oz (68g)
NDC 61578-215-01
pH+ HA NANO
U.S PATENTS NO. 9,427,384 and 10,143,633
Questions or comments?
800.503.0625
carifree.com
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Manufactured by Oral BioTech
Albany, Oregon 97321 USA
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26146 50M 8.22


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■ Children under 6 years of age: consult a dental professional.
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/CariFree
@_carifree
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You Tube
/carifree
PRO GEL 5000
1.1% NEUTRAL
SODIUM FLUORIDE
ANTI-CAVITY TOOTHPASTE
Rx only
citrus
pH elevated
2.4 oz (68g)
NDC 61578-216-01
pH+ HA NANO
U.S PATENTS NO. 9,427,384 and 10,143,633
Questions or comments?
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CARIFREE®

PRO GEL 5000

1.1% NEUTRAL
SODIUM FLUORIDE
ANTI-CAVITY TOOTHPASTE

Rx only

mint

2.4 oz (68g)

NDC 61578-215-01

Description: Self-topical neutral fluoride gel containing 1.1% sodium fluoride for use as a dental caries preventive in adults and pediatric patients.

Indications and Usage: For once daily self-applied topical use as a dental caries preventive in adults and pediatric patients 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: Follow these instructions unless otherwise instructed by your dental professional. Adults and pediatric patients 6 years of age or older, apply a thin ribbon to a toothbrush. Brush daily for two minutes in place of your regular toothpaste. After use, adults expectorate. For best results, do not eat, drink, or rinse for 30 minutes. Pediatric patients, ages 6–16, expectorate after use and rinse mouth thoroughly. See package insert for further information.

pH+® HA™ NANO

U.S. PATENTS NO. 9,427,384 and 10,143,633

Questions or comments?
800.503.0625

carifree.com

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Manufactured by Oral BioTech
Albany, Oregon 97321

PRO GEL 5000 MINT

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61578-215
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	5000 ug in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
MALTITOL (UNII: D65DG142WK)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
HYDROXYETHYL CELLULOSE (3000 CPS AT 1%) (UNII: 7Q6P4JN1QT)	
MENTHOL (UNII: L7T10EIP3A)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SACCHARIN (UNII: FST467XS7D)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61578-215-01	68 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	05/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/10/2022	

PRO GEL 5000 CITRUS

sodium fluoride gel, dentifrice

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61578-216
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	5000 ug in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
MALTITOL (UNII: D65DG142WK)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
HYDROXYETHYL CELLULOSE (3000 CPS AT 1%) (UNII: 7Q6P4JN1QT)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SACCHARIN (UNII: FST467XS7D)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics			
Color	white (opaque)	**Score**	
Shape		**Size**	
Flavor	CITRUS	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61578-216-01	68 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	05/10/2022	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
unapproved drug other		05/10/2022	

Labeler - DENTAL ALLIANCE HOLDINGS LLC (195544965)

Registrant - DENTAL ALLIANCE HOLDINGS LLC (195544965)

Establishment

Name	Address	ID/FEI	Business Operations
DENTAL ALLIANCE HOLDINGS LLC		195544965	manufacture(61578-215, 61578-216)

Revised: 1/2024 DENTAL ALLIANCE HOLDINGS LLC