

**PreviDent®
5000 BOOSTER™**
(1.1% Sodium Fluoride) Prescription Strength Toothpaste

Rx Only

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 (NaF) 1.1% (w/w).

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 PreviDent® 5000 Booster brand of 1.1% sodium fluoride toothpaste in a squeeze bottle 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 patients with dysphagia. 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 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: The use of PreviDent® 5000 Booster 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: Of the total number of subjects in clinical studies of 1.1% (w/w) sodium fluoride, 15 percent were 65 and over, while 1 percent were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.⁵

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. 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 PreviDent® 5000 Booster contains approximately 2.5 mg fluoride. A 3.58 fl. oz. (106 mL) bottle contains approximately 647 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 PreviDent® 5000 Booster 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, age 6-16, expectorate after use and rinse mouth thoroughly.

REV 05/05 This is a brief summary of the prescribing information, visit www.colgateprofessional.com for full prescribing information.

Brand	Item #	Flavor	Size	List Price/Unit*
Phos-Flur®	543-1968	Cool Mint	16 oz	\$9.19
	543-1530	Bubble Gum	16 oz	\$9.19
	543-2063	Grape	16 oz	\$9.19
	543-0019	Cool Mint	50 sachets (10 mL/ea)	\$19.69
PreviDent® Booster™	543-4218	Spearmint	3.58 oz	\$7.49
	543-6616	Fruitastic™	3.58 oz	\$7.49
Peroxyl®	543-5731	Original Mint	8 oz	\$3.89
	543-8416	Original Mint	16 oz	\$6.59
	543-4492	Cool Mint	8 oz	\$3.89
	543-5968	Cool Mint	16 oz	\$6.59
Orabase®	543-3896	Original Mint	50 sachets (10 mL/ea)	\$16.39
	543-4409		.21 oz	\$3.09
Colgate Total® Professional Toothbrush	543-1444		100 unit dose sachets	\$24.19
	543-7565		Compact Head	\$1.60
Colgate Total® Floss	543-7175		Ultra Compact Head	\$1.60
	543-0012		3 yd	\$0.42

* Quantity and plan discounts available.

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Maintaining good oral hygiene is especially important during orthodontic treatment. As you know, Orthodontic brackets and wires can trap food and plaque, putting your patients at higher risk for tooth decay and potential gum problems. Many Colgate products are specially designed to support your patients' preventative care during their orthodontic treatment.

Protect your patients' healthy smile with the help of Colgate.

FLUORIDE THERAPY



Daily preventative care against white spots

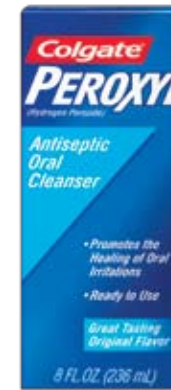
- Clinically proven to strengthen enamel to help prevent caries^{1,2}
- Reduces the appearance of white spots by 58%³
- Provides greater fluoride uptake and deeper fluoride penetration²
- Use once daily as a caries preventative



Prescription-strength toothpaste for high risk patients

- 5,000 ppm fluoride toothpaste remineralizes early root caries in 3 months⁴
- Liquid gel formula enables faster fluoride dispersion⁵
- 1 step fluoride treatment to improve patient compliance
- Use once daily to help repair early root caries or to help prevent caries in high risk patients

SOFT TISSUE FIRST AID



Promotes healing of minor mouth irritations

- 1.5% hydrogen peroxide formula reduces harmful bacteria in minor oral wounds to help prevent infection
- Gently cleans infected oral lesions by removing foreign materials that can impede the healing process
- Minty fresh, foaming action flushes away food particles from gums and braces to help give you a whole mouth clean



Maximum strength oral pain relief

- Contains 20% Benzocaine to help relieve mouth sore pain that can result from wearing braces
- Helps shield mouth sores from outside irritants
- ADA approved and alcohol-free

DAILY HYGIENE



Proven to reduce gingivitis

- Colgate Total® Professional Toothbrush is clinically proven to clean deep between teeth and along the gumline^{6,7}
- Removes plaque from multiple tooth surfaces making it ideal for Orthodontic patients^{8,9}



Comfortable and shred resistant floss

- Single strand Teflon fiber with microcrystalline coating, slides easily between tight areas without shredding

1. Frankl SN, Fleisch S and Diodati RR. The topical anticariogenic effect of daily rinsing with an acidulated phosphate fluoride solution. JADA 1972;85:882-885. 2. Aasenden R, DePaola PF and Brudevold F. Effects of daily rinsing with fluoride solutions upon dental caries and enamel fluoride. Archs Oral Biol 1972;17:1705-1714. 3. R.E. Hirschfield, Control of decalcification by use of fluoride mouthrinse. J Dent Child 1978;45:458-460. 4. Baysan A, et al. Reversal of primary root caries using dentifrice containing 5,000ppm and 1,100ppm fluoride. Caries Res. 2001;35:41-46. 5. Joziak MT, et al. Comparison of enamel fluoride uptake and fluoride release from liquid and paste dentifrice. J Dent Res. 2003; 82(Sp. Issue). Abstract 1355. 6. Singh SM, et al. J Clin Dent. 2001; 12(3):83-86. 7. Sharma NC, et al. J Clin Dent 1994; 5(4):114-118. 8. Singh SM, et al. J Clin Dent. 1993;4(D):D13-D16. 9. Sharma NC, et al. J Clin Dent 1992;3(C): C13-C20