

**PREVIDENT 5000 PLUS SPEARMINT- sodium fluoride paste, dentifrice**  
**PREVIDENT 5000 PLUS FRUITASTIC- sodium fluoride paste, dentifrice**  
**Colgate Oral Pharmaceuticals, Inc.**

*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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**PreviDent®**  
**5000 PLUS®**

**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 1.1% (w/w).

### **Inactive Ingredients**

water, sorbitol, hydrated silica, PEG-12, tetrapotassium pyrophosphate, sodium lauryl sulfate, flavor (Spearmint flavor only), xanthan gum, flavor (Fruitastic™ flavor only), sodium benzoate, sodium saccharin, titanium dioxide (Fruitastic™ flavor only), FD&C blue no. 1 (Spearmint flavor only), D&C red no. 33 (Fruitastic™ flavor 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.<sup>1-4</sup> PreviDent® 5000 Plus® brand of 1.1% sodium fluoride in a squeeze-tube is easily applied onto a toothbrush. This prescription dental cream 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 dental cream which could cause dental fluorosis. 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 Plus® 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. <sup>2,3,4</sup> 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/v) 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.

### **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 Plus® contains approximately 2.5 mg fluoride. A 1.8 oz. tube contains approximately 255 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 Plus to a toothbrush. Brush thoroughly once daily for two minutes, preferably at bedtime.
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

	<b>Spearmint</b>	<b>Fruitastic™</b>
1.8 oz. (51 g) net wt. plastic tubes.	NDC 0126-0287-66	NDC 0126-0286-66
Twin Pack (two 1.8 oz. (51 g) net wt. tubes)	NDC 0126-0287-33	

## STORAGE

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

## REFERENCES

1. American Dental Association, Council on Dental Therapeutics, Fluoride compounds, In: Accepted Dental Therapeutics, Ed. 40, Chicago, ADA, 405-407 (1984).
2. H.R. Englander et al., Clinical Anticaries Effect of Repeated Topical Sodium Fluoride Applications by Mouthpieces, JADA, 75, 638-644 (1967).
3. H.R. Englander et al., Residual Anticaries Effect of Repeated Topical Sodium Fluoride Applications by Mouthpieces, JADA, 78, 783-787 (1969).
4. Englander HR, et al: JADA 83:354-358, 1971.

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### **Colgate Oral Pharmaceuticals, Inc.**

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**PRINCIPAL DISPLAY PANEL - 51 g Tube Carton - 0287**

NDC 0126-0287-66

Colgate®

PreviDent®

5000 Plus

Rx Only

1.1%

Sodium

Fluoride

PRESCRIPTION STRENGTH

TOOTHPASTE

PROFESSIONAL

spearmint

1.8 OZ (51 g)



**PRINCIPAL DISPLAY PANEL - 51 g Tube Carton - 0286**

NDC 0126-0286-66

Colgate®

PreviDent®

5000 Plus

Rx Only

1.1%

Sodium

Fluoride

PRESCRIPTION STRENGTH

TOOTHPASTE

PROFESSIONAL

fruitastic

1.8 OZ (51 g)





## PREVIDENT 5000 PLUS SPEARMINT

sodium fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0126-0287
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	11 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	
<b>POLYETHYLENE GLYCOL 600</b> (UNII: NL4J9F21N9)	

<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	

### Product Characteristics

<b>Color</b>	BLUE (viscous)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0126-0287-66	1 in 1 CARTON	08/29/2012	
1		51 g 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		08/29/2012	

## PREVIDENT 5000 PLUS FRUITASTIC

sodium fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0126-0286
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	11 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	



<b>POLYETHYLENE GLYCOL 600</b> (UNII: NL4J9F21N9)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	

### Product Characteristics

<b>Color</b>	PINK (viscous)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0126-0286-66	1 in 1 CARTON	08/29/2012	
1		51 g 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		08/29/2012	

**Labeler** - Colgate Oral Pharmaceuticals, Inc. (968801118)

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Colgate Oral Pharmaceuticals, Inc.