

**FRAICHE 5000 PREVI- sodium fluoride,calcium hydroxyapatite gel  
True Marker 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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**Drug Facts**

**Active Ingredient (s)**

Sodium Fluoride 1.1% and Calcium Hydroxyapatite 3%

**Uses**

This 1.1% neutral sodium fluoride and 3% calcium hydroxyapatite dental gel is intended to aid in the prevention of dental decay and to help treat tooth sensitivity to cold, heat, sweets, acids, or contact.

**Warnings**

Do not swallow. Keep out of reach of children. Read the prescribing information fully before using this product. If the product is accidentally swallowed in quantities greater than would normally occur with a toothpaste, seek medical help right away. 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.

**Adverse reactions**

To report suspected adverse reactions, contact True Marker Pharmaceuticals at (877) 887-9879 or the FDA at (800) FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**Children under 6 years of age**

Consult a dentist or physician.

**Directions**

Use twice a day (morning and evening) in place of regular toothpaste or as recommended by a dentist or a physician. Adults and children 6 years of age and older. Twist off cap and remove foil seal. Apply at least a 1-inch strip of gel onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute. Spit out and rinse mouth thoroughly. Make sure to brush all sensitive areas of the teeth.  
Children under 6 years of age: Consult a dentist or physician.

## **Dosage form and Strengths**

Dental gel containing 1.1 % sodium fluoride and 3% calcium hydroxyapatite.

## **Contraindications**

Avoid use in patients with known hypersensitivity to fluoride. Do not use in pediatric patients under 6 unless directed by a dentist or physician.

## **Description**

Fraiche 5000 Previ dental gel is a flavored, pH neutral 1.1 % sodium fluoride and 3% calcium hydroxyapatite that aids in the prevention of dental decay and helps to treat sensitive teeth.

## ***Inactive Ingredients***

Water, Glycerin, Hydrated Silica, Calcium Carbonate, Xylitol, Sorbitol, Xanthan Gum, Flavor, Yucca Shidigera Root Extract, Quillaja Saponaria Bark Extract, Smilax Aristolochiaefolia Root Extract, Dioscorea Villosa Root Extract, Tocopheryl Acetate, Cocamidopropyl Betaine, Benzyl Alcohol.

## **How supplied/storage**

4.3 ounces (122g) in plastic tube. Store at room temperature 59-86° F (15-30 - °C)

## **Product label**

NDC 83592-815-04

# FRAICHE 5000 PREVI

1.1% neutral sodium fluoride /  
3% calcium hydroxyapatite  
dental gel

Gluten-free, dye-free,  
sodium lauryl sulfate-free

RX Only

4.3 oz (122g)

MINT

1.1% neutral sodium fluoride /  
3% calcium hydroxyapatite dental gel

# FRAICHE 5000 PREVI

**Indications & usage:** This 1.1% neutral sodium fluoride and 3% calcium hydroxyapatite dental gel is intended to aid in the prevention of dental decay and to help treat tooth sensitivity to cold, heat, sweets, acids, or contact.

**Dosage and administration:** Use twice a day (morning and evening) in place of regular toothpaste or as recommended by a dentist or a physician. Adults and children 12 years of age and older: Twist off cap and remove foil seal. Apply at least a 1-inch strip of gel onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute. Spit out and rinse mouth thoroughly. Make sure to brush all sensitive areas of the teeth.

**Children under 6 years of age:** Consult a dentist or physician.

**Dosage form and Strengths:** Dental gel containing 1.1% sodium fluoride and 3% calcium hydroxyapatite.

**Contraindications:** Avoid use in patients with known hypersensitivity to fluoride. Do not use in pediatric patients under 12 unless directed by a dentist or physician.

**Warnings and Precautions:** Do not swallow. Keep out of reach of children. Read the prescribing information fully before using this product. If the product is accidentally swallowed in quantities greater than would normally occur with a toothpaste, seek medical help right away. 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.

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**Description:** Fraiche 5000 Previ dental gel is a flavored, pH neutral 1.1% sodium fluoride and 3% calcium hydroxyapatite that aids in the prevention of dental decay and helps to treat sensitive teeth.

**Active ingredients:** Sodium Fluoride 1.1% and Calcium Hydroxyapatite 3%

**Inactive ingredients:** Water, Glycerin, Hydrated Silica, Calcium Carbonate, Xylitol, Sorbitol, Xanthan Gum, Flavor, Yucca Shidigera Root Extract, Quilaja Saponaria Bark Extract, Smilax Aristolochifolia Root Extract, Dioscorea Villosa Root Extract, Tocopheryl Acetate, Cocamidopropyl Betaine, Benzyl Alcohol.

**How supplied/storage:** 4.3 ounces (122g) in plastic tube. Store at room temperature 59-86°F (15-30°C)

Manufactured in USA for True Marker Pharmaceuticals Inc., Phoenix, AZ, (877) 887-0879.



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1.1% neutral sodium fluoride /  
3% calcium hydroxyapatite dental gel

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NDC 83592-815-04

# FRAICHE 5000 PREVI

1.1% neutral sodium fluoride /  
3% calcium hydroxyapatite  
dental gel

Gluten-free, dye-free,  
sodium lauryl sulfate-free

RX Only

4.3 oz (122g)

MINT

## FRAICHE 1.1% neutral sodium fluoride / 5000 PREVI 3% calcium hydroxyapatite dental gel

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**Dosage form and Strengths:** Dental gel containing 1.1% sodium fluoride and 3% calcium hydroxyapatite.

**Contraindications:** Avoid use in patients with known hypersensitivity to fluoride. Do not use in pediatric patients under 6 unless directed by a dentist or physician.

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## FRAICHE 5000 PREVI

sodium fluoride, calcium hydroxyapatite gel

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:83592-815
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

		<b>Ratio of</b>	
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Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 g in 100 g
<b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	3 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>YUCCA SCHIDIGERA WHOLE</b> (UNII: 08A0YG3VIC)	
<b>QUILLAJA SAPONARIA BARK</b> (UNII: 8N0K3807ZW)	
<b>SMILAX ARISTOLOCHIIFOLIA ROOT</b> (UNII: NR100Y25G0)	
<b>DIOSCOREA VILLOSA ROOT</b> (UNII: IWY3IWX2G8)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83592-815-04	1 in 1 CARTON	03/12/2024	
1		122 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		03/12/2024	

**Labeler** - True Marker Pharmaceuticals, Inc. (119046582)

Revised: 3/2024

True Marker Pharmaceuticals, Inc.