

FRAICHE 5000 KIDS PLUS DENTAL BUBBLE GUM- sodium fluoride,tribasic calcium phosphate 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.

Drug Facts

Active Ingredient (s)

Purpose

1.1% neutral sodium fluoride and 4% calcium hydroxyapatite

Dental gel

Uses

This 1.1% neutral sodium fluoride and 4% 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.

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 4% 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.

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.

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.

Description

Fraiche 5000 Kids Plus dental gel is a flavored, pH neutral 1.1% sodium fluoride and 4% 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 83592-818-04

FRAICHE 5000 KIDS PLUS DENTAL GEL

1.1% neutral sodium fluoride /
4% calcium hydroxyapatite
dental gel

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

RX Only

BUBBLE GUM

1.41 oz (40gm)

1.1% neutral sodium fluoride /
4% calcium hydroxyapatite dental gel

FRAICHE 5000 KIDS PLUS
DENTAL GEL

Indications & Usage: This 1.1% neutral sodium fluoride and 4% 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 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 4% 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.

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.

Adverse Reactions: To report suspected adverse reactions, contact True Marker Pharmaceuticals at (877) 887-9679 or the FDA at (800) FDA-1088 or www.fda.gov/medwatch.

Description: Fraiche 5000 Kids Plus dental gel is a flavored, pH neutral 1.1% sodium fluoride and 4% 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 4%

Inactive Ingredients: Water, Glycerin, Hydrated Silica, Calcium Carbonate, Xylitol, Sorbitol, Xanthan Gum, Flavor, Yucca Shidigera Root Extract, Quillaja Saponaria Bark Extract, Smilax Aristochloaefolia 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) 887-9679.



1.1% neutral sodium fluoride /
4% calcium hydroxyapatite dental gel

FRAICHE 5000 KIDS PLUS
DENTAL GEL

NDC 83592-818-04

FRAICHE 5000 KIDS PLUS DENTAL GEL

1.1% neutral sodium fluoride /
4% calcium hydroxyapatite
dental gel

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

RX Only

BUBBLE GUM

1.41 oz (40gm)

FRAICHE 5000 KIDS PLUS DENTAL GEL 1.1% neutral sodium fluoride / 4% calcium hydroxyapatite dental gel

Indications & Usage: This 1.1% neutral sodium fluoride and 4% 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 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 4% 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.

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.

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.

Description: Fraiche 5000 Kids Plus dental gel is a flavored, pH neutral 1.1% sodium fluoride and 4% 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 4%

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: 4.41 ounces (40g) in plastic tube. Store at room temperature 59-88°F (15-30°C)

Manufactured in USA for True Marker Pharmaceuticals Inc., Phoenix, AZ, (877) 887-9879.



FRAICHE 5000 KIDS PLUS DENTAL BUBBLE GUM

sodium fluoride, tribasic calcium phosphate gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:83592-818
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 g in 100 g
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
XYLITOL (UNII: VCQ006KQ1E)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
YUCCA SCHIDIGERA WHOLE (UNII: 08A0YG3VIC)	
QUILLAJA SAPONARIA BARK (UNII: 8N0K3807ZW)	
SMILAX ARISTOLOCHIIFOLIA ROOT (UNII: NR100Y25G0)	
DIOSCOREA VILLOSA ROOT (UNII: IWY3IWX2G8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83592-818-04	1 in 1 CARTON	08/26/2024	
1		40 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		08/26/2024	

Labeler - True Marker Pharmaceuticals, Inc. (119046582)

Revised: 9/2024

True Marker Pharmaceuticals, Inc.