FRAICHE 5000 SENSITIVE- sodium fluoride,potassium nitrite 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)

Sodium Fluoride 1.1% and Potassium Nitrate 4.5%.

Uses

This 1.1% neutral sodium fluoride and 4.5% potassium nitrate 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 no 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.

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 4.5% potassium nitrate.

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 hydroxy apatite 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 83592-816-04

FRAICHE
5000 SENSITIVE

1.1% neutral sodium fluoride / 4.5% potassium nitrate dental gel

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

RX Only

4.3 oz (122g)

MINT

FRAICHE 5000 SENSITIVE **1.1% neutral sodium fluoride / 4.5% potassium nitrate dental gel**

Indications & usage: This is a fluoride and potassium nitrate dental gel 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 4.5% potassium nitrate.

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 no 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 Sensitive dental gel is a flavored, pH neutral 1.1% sodium fluoride and 4.5% potassium nitrate that aids in the prevention of dental decay and helps to treat sensitive teeth.

Active ingredients: Sodium Fluoride 1.1% and Potassium Nitrate 4.5%

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)

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

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FRAICHE 5000 SENSITIVE

sodium fluoride,potassium nitrite gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:83592-816
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
POTASSIUM NITRITE (UNII: 794654G42L) (NITRITE ION - UNII:J39976L608)	POTASSIUM NITRITE	4.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
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:83592-816-04	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.