FRAICHE 5000 DENTAL MINT- sodium fluoride 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

1.1% neutral sodium fluoride

Purpose

Dental gel

Uses

This is a fluoride dental gel intended for use as dental caries preventive in adults and pediatric patients.

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. 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.

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.

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.

Other information

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.

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.

Product label

FRAICHE 5000 DENTAL MINT
sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:83592-814
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

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:83592-814-04	1 in 1 CARTON	08/12/2024	
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		08/12/2024	

Labeler - True Marker Pharmaceuticals, Inc. (119046582)

Revised: 9/2024 True Marker Pharmaceuticals, Inc.