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

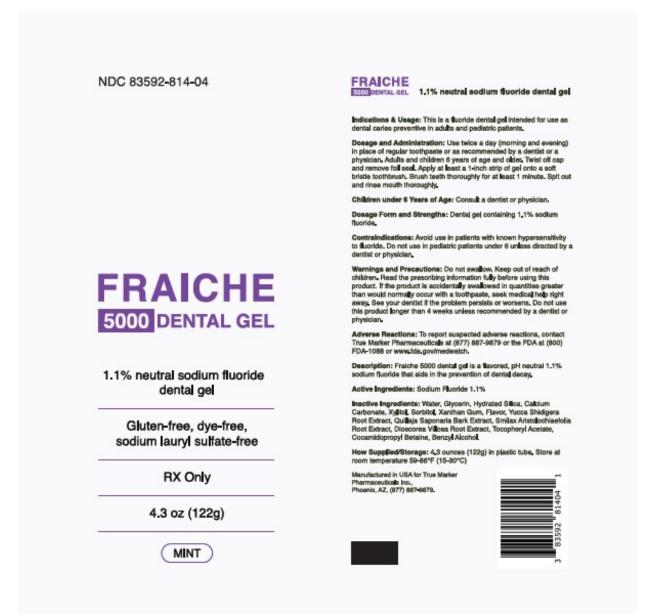
To report suspected adverse reactions, contact True Marker Pharmaceuticals at (877)

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

Pr	oduct Infor	mation					
Product Type			HUMAN PRESCRIPTION DRUG	Item Code (Source)		NDC:83592-814	
۲o	ute of Admini	stration	TOPICAL				
Ac [.]	tive Ingredi	ent/Active	Moiety				
	Ingredient Name Basis of Stre						Strength
CODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION							1.1 g in 100
na	nctive Ingre	dients					
Ingredient Name							Strength
VATER (UNII: 059QF0KO0R)							
GLΥ	CERIN (UNII: PD	C6A3C0OX)					
IYI	RATED SILICA	(UNII: Y607T40	68P9)				
CAL	CIUM CARBON	ATE (UNII: HOG	9379FGK)				
YL	ITOL (UNII: VCQ	006KQ1E)					
501	RBITOL (UNII: 50)6T60A25R)					
(A)	ITHAN GUM (UN	III: TTV12P4NEE	E)				
(UC	CA SCHIDIGER	A WHOLE (UN	II: 08A0YG3VIC)				
QU	LLAJA SAPONA	RIA BARK (UNI	: 8N0K3807ZW)				
5 M	LAX ARISTOLO	CHIIFOLIA RO	OT (UNII: NR100Y25G0)				
010	SCOREA VILLO	SA ROOT (UNI	: IWY3IWX2G8)				
AL	РНАТОСОРНЕ	ROL ACETATE	(UNII: 9E8X80D2L0)				
0	CAMIDOPROPY	L BETAINE (UN	III: 50CF3011KX)				
BEN	ZYL ALCOHOL	(UNII: LKG8494	₩BH)				
Pa	ckaging						
ŧ	Item Code	Pao	ckage Description		eting Start Date	Mark	eting End Date
	IDC:83592-814- 4	1 in 1 CARTON		08/12/2024			
L		122 g in 1 TUE Product	BE; Type 0: Not a Combination				
Ma	arketing	Informat	ion				
	Marketing Category	Applicat	tion Number or Monograph Citation	Mar	keting Start Date	Mar	keting End Date
ına	pproved drug er			08/12/2	2024		

Labeler - True Marker Pharmaceuticals, Inc. (119046582)