FRAICHE KIDS BUBBLE GUM MOUTHWASH- sodium fluoride liquid True Marker Pharmaceuticals, Inc.

Drug Facts

Active Ingredient

SODIUM FLUORIDE 0.05% (0.02% w/v fluoride ion)

Purpose

Dental Caries Preventive

Uses □

Aids in the prevention of dental cavities.

Warnings

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Use once a day after brushing your teeth with a toothpaste
- Remove cap
- Hold bottle upright and squeeze. Fill to FILL LINE (10mL)
- Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out
- Do not swallow the rinse
- Do not eat or drink for 30 minutes after rinsing
- Instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
- Supervise children as necessary until capable of using without supervision
- Children under 6 years of age: consult a dentist or doctor

Other information

- Store at controlled room temperature, 68-77°F (20-25°C).
- Do not use if safety seal is broke or missing.

Inactive Ingredients

Cetylpyridinium chloride, dipotassium glycyrrhizinate, disodium phosphate, flavor, glycerin, poloxamer 407, polysorbate 20, propylene glycol, sodium benzoate, sodium

This product does not contain ethyl alcohol.

Product label

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Indications and Use

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Inactive Ingredients

Cetylpyridinium chloride, dipotassium glycyrrhizinate, disodium phosphate, flavor, glycerin, poloxamer 407, polysorbate 20, propylene glycol, sodium benzoate, sodium phosphate, sorbitol, stevia rebaudiana leaf/stem extract, water, xylitol.

This product does not contain ethyl alcohol.

Manufactured in USA for: True Marker Pharmaceuticals, Inc., Phoenix, AZ. 1-888-811-2634



NDC 83592-802-10



0.05% (0.02% w/v Fluoride Ion)

Helps Prevent Cavities & Tooth Decay

Strengthens & Protects Teeth

BUBBLE GUM

IMPORTANT:

Read directions for proper use.

Dye Free I Gluten Free I Paraben Free Alcohol Free

10.14 fl. oz. (300mL)

FRAICHE KIDS BUBBLE GUM MOUTHWASH

sodium fluoride liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83592-802

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.05 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)			
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)			
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SODIUM PHOSPHATE (UNII: SE337SVY37)			
SORBITOL (UNII: 506T60A25R)			
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)			
WATER (UNII: 059QF0KO0R)			
XYLITOL (UNII: VCQ006KQ1E)			

l	P	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
		NDC:83592- 802-10	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2024			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M021	07/01/2024		

Labeler - True Marker Pharmaceuticals, Inc. (119046582)

Revised: 6/2024 True Marker Pharmaceuticals, Inc.