

FRAICHE STANNOUS FLUORIDE RINSE, FRUIT PUNCH FLAVOR- stannous fluoride liquid

True Marker Pharmaceuticals, Inc.

Drug Facts

Active Ingredient (s)

Stannous fluoride, 0.63%

Purpose

Anticavity/Antigingivitis

Uses □

Aids in the prevention of dental decay

- helps prevent gingivitis
- helps interfere with harmful effects of plaque associated with gingivitis.

Warnings

- Keep out of reach of children under 6 years of age.
- If more than used for rinsing is swallowed, get medical help or contact a Poison Control Center right away. Do not swallow.

Directions

- Do not use before mixing with water.
- Adults and children 6 years of age and older:
- Use once a day after brushing your teeth with a toothpaste.
- Open the bottle by twisting the cap counter clockwise
- Pour 1/8 fl. oz. into a cup. Add water to line (1 fl. oz.) on cup.
- Mix using bristle end of toothbrush
- Vigorously swish rinse between your teeth for 1 min. and then spit out.
- Do not swallow the rinse
- Do not eat or drink for 30 min. after rinsing.
- Instruct children under 12 in good rinsing habits to minimize swallowing. Supervise children as necessary until capable of using without supervision.
- Children under 6: Consult a dentist or doctor.

Other information

- Store at room temperature 59-86°F (15-30°C)
- This product may produce surface staining of the teeth. Adequate tooth brushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.

Inactive Ingredients

Edetic Acid, Flavor, Glycerin, Saccharin Sodium, Xylitol

Product label



NDC 83592-801-04

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Manufactured in USA for:
 True Marker Pharmaceuticals, Inc.,
 Phoenix, AZ.



FRAICHE

STANNOUS FLUORIDE

RINSE

0.63% Stannous Fluoride
 Concentrate with Xylitol

Alcohol Free

FRUIT PUNCH

IMPORTANT:
 Read directions for proper use.

MADE IN USA

Dye Free | Gluten Free | Paraben Free

4 fl. oz. (118ml)

FRAICHE STANNOUS FLUORIDE RINSE, FRUIT PUNCH FLAVOR

stannous fluoride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83592-801
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.63 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
EDETIC ACID (UNII: 9G34HU7RV0)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XYLITOL (UNII: VCQ006KQ1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83592-801-04	1 in 1 CARTON	04/04/2024	
1		118 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	04/04/2024	

Labeler - True Marker Pharmaceuticals, Inc. (119046582)

Revised: 4/2024

True Marker Pharmaceuticals, Inc.