

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

**True Marker Pharmaceuticals, Inc.**

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**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 to the first line (0.159 oz) on cup. Add water to second line (1fl 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

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



NDC 83592-801-04

# 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

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

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>EDETIC ACID</b> (UNII: 9G34HU7RV0)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>XYLITOL</b> (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: 7/2024

True Marker Pharmaceuticals, Inc.