

**FRAICHE STANNOUS FLUORIDE RINSE, SPEARMINT 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

<h4>Drug Facts</h4>	<p>NDC 83592-800-04</p>				
<table border="1"> <thead> <tr> <th>Active Ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Stannous fluoride, 0.63%</td> <td>Anticavity/Antigingivitis</td> </tr> </tbody> </table>	Active Ingredient	Purpose	Stannous fluoride, 0.63%	Anticavity/Antigingivitis	<h1>FRAICHE</h1> <h2>STANNOUS FLUORIDE</h2> <h3>RINSE</h3>
Active Ingredient	Purpose				
Stannous fluoride, 0.63%	Anticavity/Antigingivitis				
<h4>Uses</h4> <p>Aids in the prevention of dental decay • helps prevent gingivitis • helps interfere with harmful effects of plaque associated with gingivitis.</p>	<p>0.63% Stannous Fluoride Concentrate with Xylitol</p>				
<h4>Warnings</h4> <p>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.</p>	<p>Alcohol Free</p> <p><b>SPEARMINT</b></p>				
<h4>Directions</h4> <ul style="list-style-type: none"> <li>• Do not use before mixing with water.</li> <li>• Adults and children 6 years of age and older:             <ul style="list-style-type: none"> <li>- Use once a day after brushing your teeth with a toothpaste.</li> </ul> </li> <li>• Open the bottle by twisting the cap counter clockwise.</li> <li>• Pour 1/8 fl. oz. into a cup. Add water to line (1 fl. oz.) on cup.</li> <li>• Mix using bristle end of toothbrush.</li> <li>• Vigorously swish rinse between your teeth for 1 min. and then spit out.</li> <li>• Do not swallow the rinse.</li> <li>• Do not eat or drink for 30 min. after rinsing.</li> <li>• Instruct children under 12 in good rinsing habits to minimize swallowing. Supervise children as necessary until capable of using without supervision.</li> <li>• <b>Children under 6:</b> Consult a dentist or doctor.</li> </ul>	<p><b>IMPORTANT:</b> Read directions for proper use.</p>				
<h4>Other Information</h4> <ul style="list-style-type: none"> <li>• Store at room temperature 59-86°F (15-30°C)</li> <li>• 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.</li> </ul>	<p><b>MADE IN USA</b> Dye Free   Gluten Free   Paraben Free</p>				
<h4>Inactive Ingredients</h4> <p>Edetic Acid, Flavor, Glycerin, Saccharin Sodium, Xylitol</p>	<p>4 fl. oz. (118ml)</p>				
<p>Manufactured in USA for: True Marker Pharmaceuticals, Inc., Phoenix, AZ.</p> 					



## FRAICHE STANNOUS FLUORIDE RINSE, SPEARMINT FLAVOR

stannous fluoride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83592-800
<b>Route of Administration</b>	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:83592-800-04	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.