

**BURKHART- stannous fluoride concentrate**  
**Burkhart Dental Supply 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.*

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**Active Ingredient:**

Stannous Fluoride 0.63% Concentrate (0.12% w/v fluoride ion).

**Purpose:**

Anticavity, antigingivitis, antihypersensitivity mouthrinse

**Indications and Usage:**

Aids in the prevention of dental decay. Helps prevent gingivitis. Helps control plaque bacteria. Increases protection against painful tooth sensitivity. This product must be used under the supervision of a dentist.

**Warnings:**

- **Keep out of reach of children.**

Do not swallow. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

- Do not use until diluted.

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.

**Directions:**

**Adults and children 6 years of age and older:**

- Do not use before mixing with water. Use immediately after preparing the rinse.
- Remove cap and replace with pump.
- Rotate spout container clockwise to extend.
- Depress pump until rinse comes to the tip of the pump.
- Depress pump twice into cup provided (1/8oz). Add water to line (1oz) on cup. Mix well.
- Vigorously swish 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 the use of this product (to minimize swallowing). Supervise children as necessary until capable of using without supervision.

**Children under 6 years of age:**

- Consult a dentist or doctor.

## Inactive Ingredients:

Flavor, Glycerin, Methyl paraben, Propyl paraben and Sodium Saccharin.

## Other Information:

Store at controlled room temperature 59° - 86°F (15°-30°C). Protect from freezing.

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MADE IN THE USA



Reorder No. 72721433

### Directions:

#### Adults and children 6 years of age and older:

- Do not use before mixing with water. Use immediately after preparing the rinse.
- Remove cap and replace with pump.
- Rotate spout counter clockwise to extend.
- Depress pump until rinse comes to the tip of the pump.
- Depress pump twice into cup provided (1/8oz). Add water to line (1oz) on cup. Mix well.
- Vigorously swish 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.
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Manufactured for Burkhart Dental Supply  
2502 S. 78th Street  
Tacoma, Washington 98409  
(800) 562-8176  
www.burkhartdental.com

## HOME CARE FLUORIDE RINSE

0.63% Stannous Fluoride  
Concentrated Solution

Alcohol Free

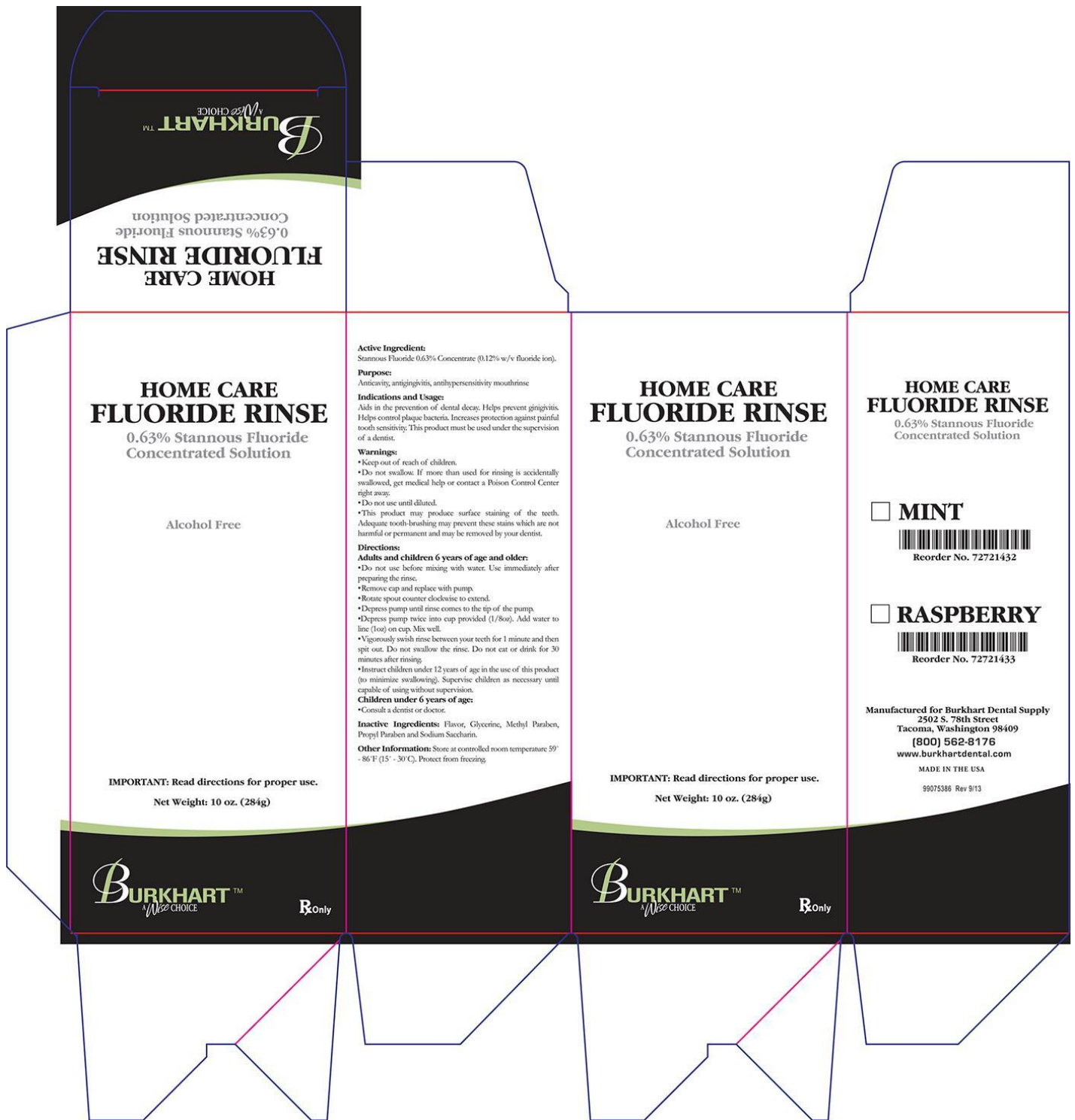
## RASPBERRY

**IMPORTANT: Read directions for proper use.**

Net Weight: 10 oz. (284g)

**BURKHART**™  
A Wise CHOICE

R Only



# BURKHART

stannous fluoride concentrate

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:43498-201
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	0.3408 g in 284 g	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
GLYCERIN (UNII: PDC6A3C0OX)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
<b>Product Characteristics</b>				
Color	white (heavy liquid)	Score		
Shape		Size		
Flavor	RASPBERRY	Imprint Code		
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43498-201-10	284 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2013	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		02/01/2013		

**Labeler** - Burkhart Dental Supply Inc (027532357)

Revised: 2/2022

Burkhart Dental Supply Inc