

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.

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. 72721432

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

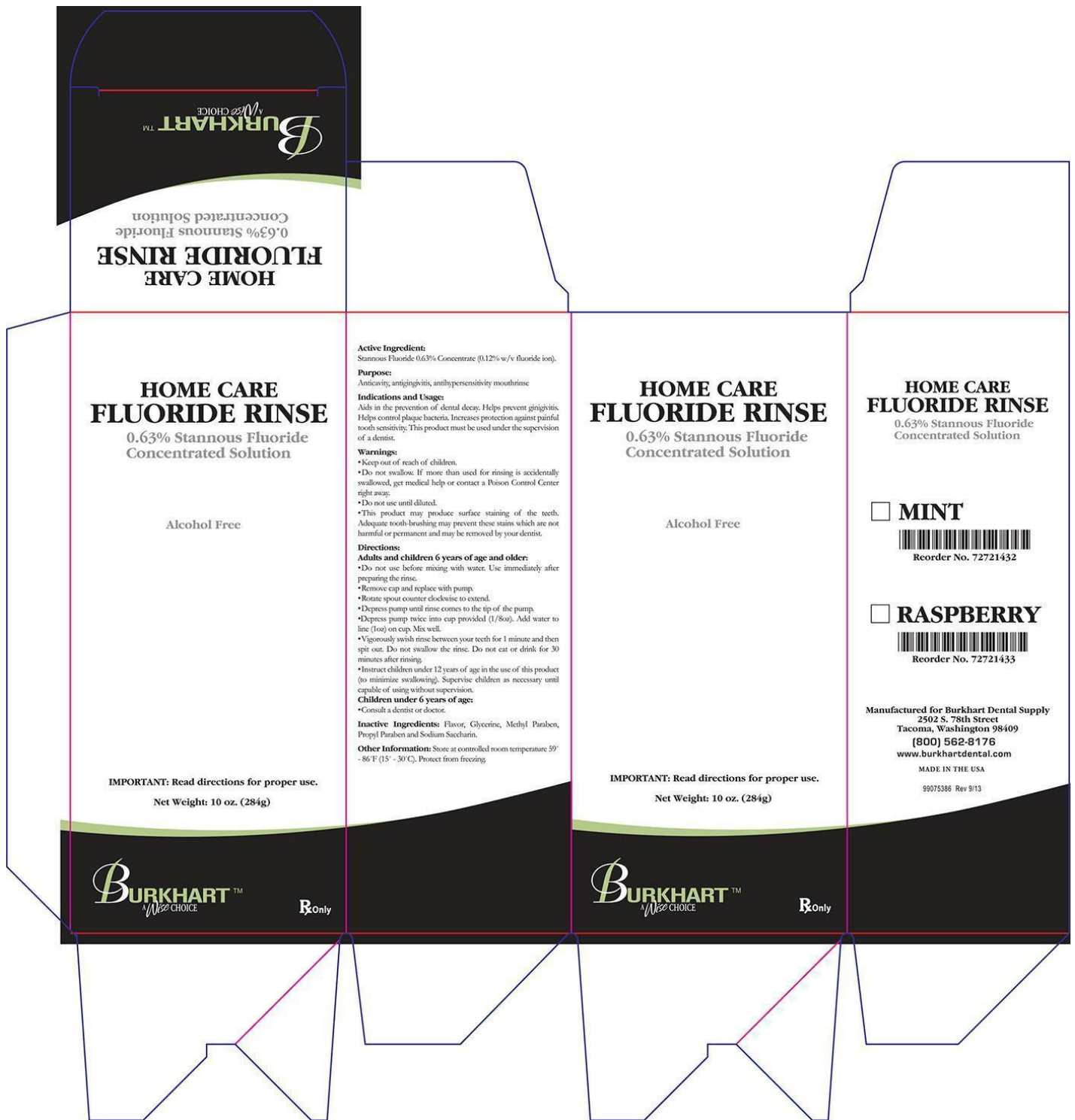
MINT

IMPORTANT: Read directions for proper use.

Net Weight: 10 oz. (284g)

BURKHARTTM
A WISE CHOICE

R_xOnly



BURKHART

stannous fluoride concentrate

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:43498-200
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU4080)		FLUORIDE ION	0.3408 g in 284 g	
Inactive Ingredients				
Ingredient Name		Strength		
GLYCERIN (UNII: PDC6A3C00X)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
Product Characteristics				
Color	white (heavy liquid)	Score		
Shape		Size		
Flavor	PEPPERMINT	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43498-200-10	284 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2013	
Marketing Information				
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