

BURKHART- stannous fluoride gel
Burkhart Dental Supply Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient:

Stannous Fluoride 0.4%

Purpose:

Fluoride preventive treatment gel.

Uses:

- Home Care is a stable, water-free fluoride gel for home use.
- Aids in the prevention of dental decay.

Keep out of reach of children.

Warnings:

- If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.
- This product may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.
- This is a fluoride preventive treatment gel, not a toothpaste. Read directions carefully before using.

Directions:

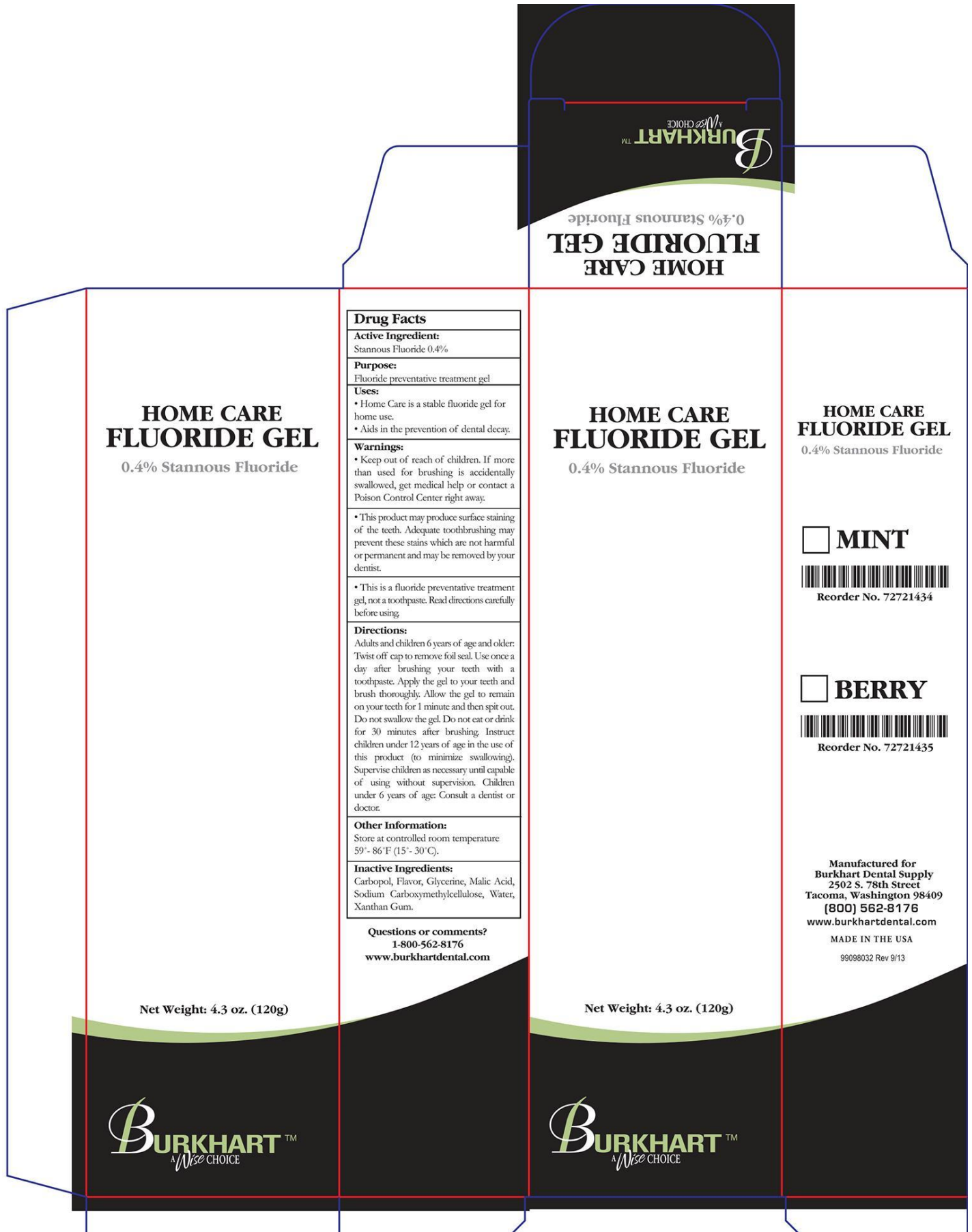
Adults and children 6 years of age and older: Twist off cap and remove foil seal. Use once a day after brushing your teeth with a toothpaste. Apply the gel to your teeth and brush thoroughly. Allow the gel to remain on your teeth for 1 minute and then spit out. Do not swallow the gel. Do not eat or drink for 30 minutes after brushing. 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.

Other Information:

Store at controlled room temperature 59° - 86°F (15° - 30°C)

Inactive Ingredients:

Carbopol, Flavor, Glycerine, Malic Acid, Sodium Carboxymethylcellulose, Water, Xanthan Gum.




 0.4% Stannous Fluoride
HOME CARE FLUORIDE GEL

**HOME CARE
FLUORIDE GEL**
 0.4% Stannous Fluoride

**HOME CARE
FLUORIDE GEL**
 0.4% Stannous Fluoride


**HOME CARE
FLUORIDE GEL**
 0.4% Stannous Fluoride

Drug Facts
Active Ingredient: Stannous Fluoride 0.4%
Purpose: Fluoride preventative treatment gel
Uses: <ul style="list-style-type: none"> • Home Care is a stable fluoride gel for home use. • Aids in the prevention of dental decay.
Warnings: <ul style="list-style-type: none"> • Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away. • This product may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist. • This is a fluoride preventative treatment gel, not a toothpaste. Read directions carefully before using.
Directions: Adults and children 6 years of age and older: Twist off cap to remove foil seal. Use once a day after brushing your teeth with a toothpaste. Apply the gel to your teeth and brush thoroughly. Allow the gel to remain on your teeth for 1 minute and then spit out. Do not swallow the gel. Do not eat or drink for 30 minutes after brushing. 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.
Other Information: Store at controlled room temperature 59° - 86°F (15° - 30°C).
Inactive Ingredients: Carbopol, Flavor, Glycerine, Malic Acid, Sodium Carboxymethylcellulose, Water, Xanthan Gum.

Questions or comments?
 1-800-562-8176
www.burkhartdental.com

MINT

 Reorder No. 72721434

BERRY

 Reorder No. 72721435

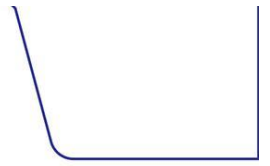
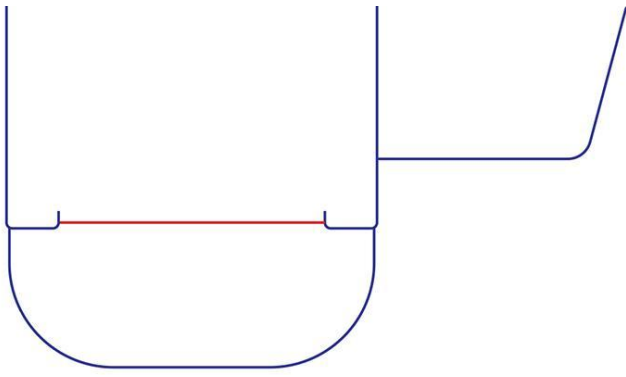
Manufactured for
Burkhardt Dental Supply
 2502 S. 78th Street
 Tacoma, Washington 98409
(800) 562-8176
www.burkhartdental.com
 MADE IN THE USA
 99098032 Rev 9/13

Net Weight: 4.3 oz. (120g)

Net Weight: 4.3 oz. (120g)







Drug Facts

Active Ingredient: Stannous Fluoride 0.4%.....**Purpose:** Fluoride preventative treatment gel

Uses:

- Home Care is a stable fluoride gel for home use.
- Aids in the prevention of dental decay.

Warnings:

- Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.
- This product may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.
- This is a fluoride preventative treatment gel, not a toothpaste. Read directions carefully before using.

Directions:

Adults and children 6 years of age and older: Twist off cap to remove foil seal. Use once a day after brushing your teeth with a toothpaste. Apply the gel to your teeth and brush thoroughly. Allow the gel to remain on your teeth for 1 minute and then spit out. Do not swallow the gel. Do not eat or drink for 30 minutes after brushing. 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.

Other Information: Store at controlled room temperature 59° - 86°F (15° - 30°C).

Inactive Ingredients: Carbopol, Flavor, Glycerine, Malic Acid, Sodium Carboxymethylcellulose, Water, Xanthan Gum.

Questions or comments?
1-800-562-8176
www.burkhartdental.com

Manufactured for
Burkhart Dental Supply
2502 S. 78th Street
Tacoma, Washington 98409
(800) 562-8176
www.burkhartdental.com

MADE IN THE USA

99098031 Rev 9/13

HOME CARE FLUORIDE GEL

0.4% Stannous Fluoride

MINT



Reorder No. 72721434

Net Weight: 4.3 oz. (120g)

BURKHARTTM
A WISE CHOICE

BURKHART

stannous fluoride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43498-250
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.116 g in 120 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
MALIC ACID (UNII: 817L1N4CKP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	white (Cloudy)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43498-250-04	120 g in 1 TUBE; Type 0: Not a Combination Product	09/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/05/2013	

Labeler - Burkhart Dental Supply Inc (027532357)