

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:

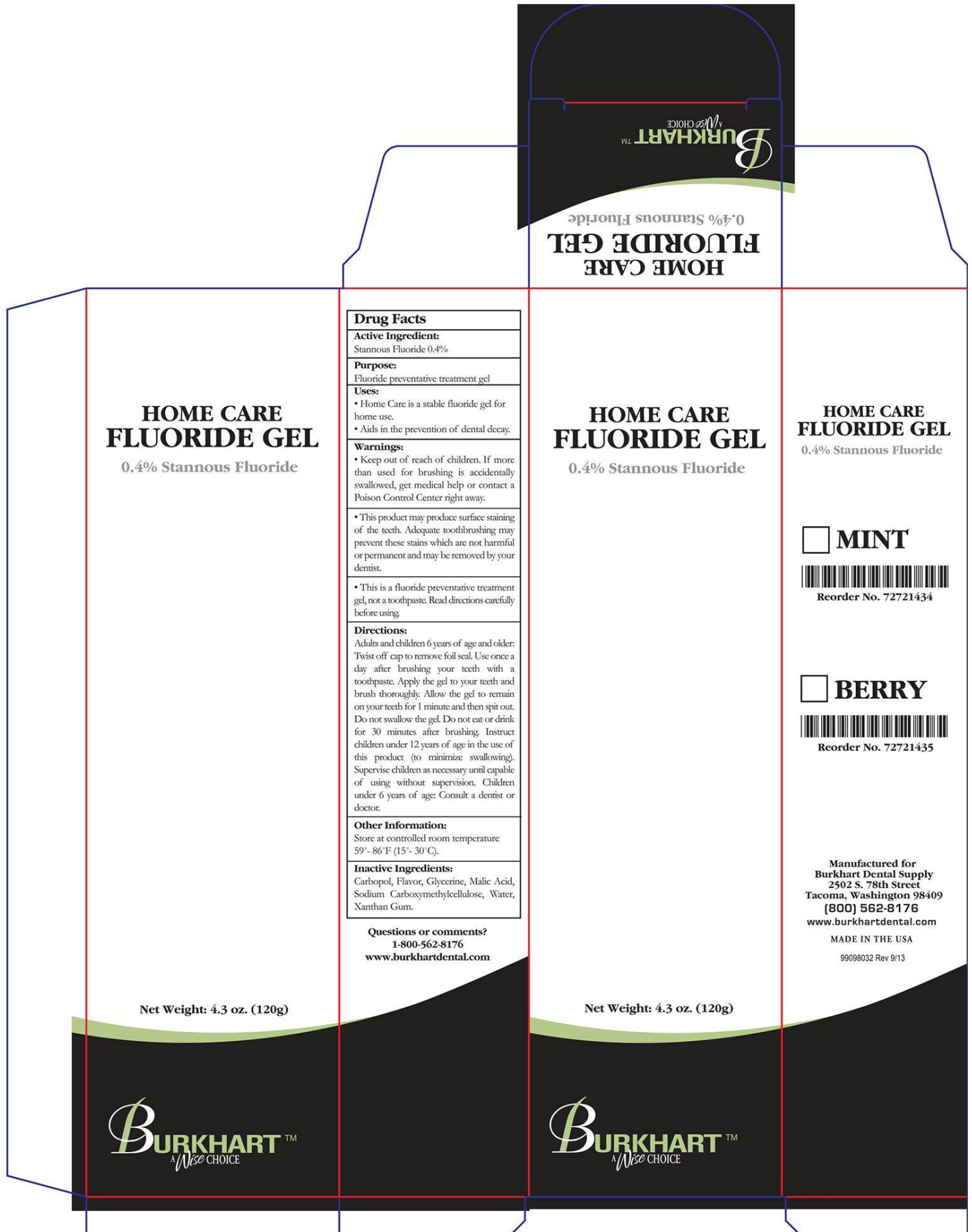
Adults and children 6 years of age and older: Twist off cap and remove foil seal. Use once a day after brushing your teeth with a toothpaste. Apply the gel to your teeth and brush thoroughly. Allow the gel to remain on your teeth for 1 minute and then spit out. Do not swallow the gel. Do not eat or drink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



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

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0.4% Stannous Fluoride

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MINT



Reorder No. 72721434

BERRY



Reorder No. 72721435

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

MADE IN THE USA

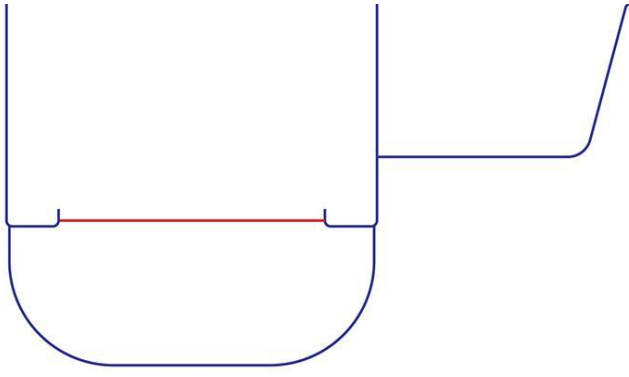
99098032 Rev 9/13

Net Weight: 4.3 oz. (120g)

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BURKHART™
A Wise CHOICE

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99098032 Rev 9/13

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0.4% Stannous Fluoride

BERRY



Reorder No. 72721435

Net Weight: 4.3 oz. (120g)

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A WISE CHOICE

BURKHART

stannous fluoride gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:43498-251 |
| 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 | BERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:43498-251-04 | 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)