

BURKHART NEUTRAL- sodium fluoride gel

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:

1.1% Sodium Fluoride.

Purpose:

Aids in prevention of dental caries and hypersensitivity. Use as directed by your dentist.

Warnings:

Do not swallow. To avoid ingestion, supervision is required while children are using the product. Keep out of reach of children.

Directions:

Adults and children 6 years of age and older:

- Twist off cap to remove foil seal.
- Use once daily after brushing teeth thoroughly with toothpaste.
- Apply a small amount to a toothbrush and brush thoroughly on all tooth surfaces for at least 1 minute.
- Expectorate, do not swallow, do not eat, drink or rinse for at least 30 minutes.

Children under 6 years of age:

- Consult a dentist or physician.

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

Inactive Ingredients:

Calcium Caseinate, Citric Acid, Flavor, Glycerine, Glydant, Sodium Benzoate, Sodium Hexameta Phosphate, Sodium Saccharine, TriCalcium Phosphate, Vitamin E, Water, Xanthan Gum, Xylitol.

HOME CARE NEUTRAL GEL

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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

99098034 Rev 9/13

HOME CARE NEUTRAL GEL

1.1% Sodium Fluoride

CHERRY



Reorder No. 72721436

R_x Only

Net Weight: 4.3 oz. (120g)

BURKHART™
A Wise CHOICE

HOME CARE NEUTRAL GEL

1.1% Sodium Fluoride

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Reorder No. 72721436

MINT



Reorder No. 72721437

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99075162 Rev 9/13



BURKHART NEUTRAL

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:43498-301
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.597 g in 120 g

Inactive Ingredients

Ingredient Name	Strength
CASEIN (UNII: 48268V50D5)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	white (opaque)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43498-301-04	120 g in 1 TUBE; Type 0: Not a Combination Product	02/11/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/11/2019	

Labeler - Burkhart Dental Supply Inc (027532357)

Revised: 2/2019

Burkhart Dental Supply Inc