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 physcian.

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

1.1% Sodium Fluoride

Active Ingredient: 1.1% Sodium Fluoride.

Purpose: Aids in the 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.
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- Apply a small amount to a toothbrush and brush thoroughly on all tooth surfaces for at least 1 minute.
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Children under 6 years of age:

Consult a dentist or physician.

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

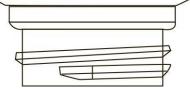
Inactive Ingredients: Calcium Caseinate, Citric Acid, Flavor, Glycerine, Glydant, Sodium Benzoate, Sodium Hexameta Phosphate, Sodium Saccharine, TriCalcium Phosphate, Vitamin E, Water, Xanthan Gum, Xylitol.

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

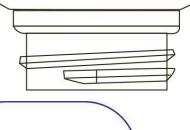


Reorder No. 72721436

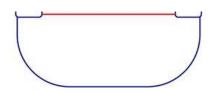
Ronly

Net Weight: 4.3 oz. (120g)





HOME CARE HOME CARE **NEUTRAL GEL NEUTRAL GEL HOME CARE HOME CARE NEUTRAL GEL** 1.1% Sodium Fluoride **NEUTRAL GEL** 1.1% Sodium Fluoride Active Ingredient: 1.1% Sodium Fluoride 1.1% Sodium Fluoride 1.1% Sodium Fluoride. Purpose: Aids in the prevention of dental caries and hypersensitivity. Use as directed by your dentist. **CHERRY** Warnings: Do not swallow. To avoid ingestion, supervision is required while children are using the product. Keep out of reach of children. Reorder No. 72721436 Directions: Adults and children 6 years of age and older: **MINT** · 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. Other Information: Store at controlled room temperature 59°-86°F (15°-30°C). Inactive Ingredients: Calcium Caseinate, Citric Acid, Flavor, Manufactured for Burkhart Dental Supply 2502 S. 78th Street Tacoma, Washington 98409 Glycerine, Glydant, Sodium Benzoate, Sodium Hexameta Phosphate, Sodium Saccharine, TriCalcium Phosphate, Vitamin E, Water, Xanthan Gum, (800) 562-8176 www.burkhartdental.com Xylitol. MADE IN THE USA 99075162 Rev 9/13 Net Weight: 4.3 oz. (120g) Net Weight: 4.3 oz. (120g)



BURKHART NEUTRAL

sodium fluoride gel

Product Information	oduct 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: 48268 V50 D5)		
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)		
GLYCERIN (UNII: PDC6A3C0OX)		
DMDM HYDANTO IN (UNII: BYR0546TOW)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM POLYMETAPHO SPHATE (UNII: P1BM4ZH95L)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
TRICAL CIUM PHO SPHATE (UNII: K4C08 XP666)		
.ALPHATO COPHERO L (UNII: H4N8 55PNZ1)		
WATER (UNII: 059QF0KO0R)		
XANTHAN GUM (UNII: TTV12P4NEE)		
XYLITOL (UNII: VCQ006KQ1E)		

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

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	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