#### GRAFCO APPLICATOR 15 CM- silver nitrate stick GF Health Products, 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.

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#### **INDICATIONS AND USAGE:**

INDICATIONS: For cauterization of skin or mucous membrane and for removing warts and granulated tissue.

#### DOSAGE AND ADMINISTRATION:

Moisten the applicator tip with distilled, deionized or purified water and apply the silver nitrate to the affected area by holding, rubbing, or rotating the tip along the affected tissue. The strength of the action is controlled by the dilution with distilled, deionized or purified water. One silver nitrate applicator is generally sufficient for each application. The action of the silver nitrate can be stopped by washing the area with saline solution (0.9% sodium chloride). *Using saline solution to wet the applicator tips, or residual saline from wound flushing/washing will interfere with the action of silver nitrate resulting in cauterization failure*. Only use distilled, deionized or purified water to wet applicator tips. Blot dry wounds that have been flushed/washed with saline prior to applying silver nitrate.

#### **CONTRAINDICATIONS:**

Silver salts stain tissue black due to deposition of reduced silver. The stain gradually disappears within a period of two weeks. Prolonged ingestion or absorption of silver compounds leads to deposition of silver in connective tissues, producing a slate-blue discoloration of the skin known as argyria. This discoloration may also appear on mucous membranes such as the margins of gums. The sclera of the eye is also stained.

#### WARNINGS AND PRECAUTIONS:

**WARNING: KEEP OUT OF REACH OF CHILDREN.** The active ingredients are poisonous and may be fatal when ingested in sufficient doses. The symptoms include toxic gastroenteritis, which may lead to coma, convulsion, paralysis and profound alteration of respiration. If poisoning occurs, immediately consult a physician.

**WARNING: DO NOT USE ON THE EYES.** In case of eye contact, hold eyes open and immediately flush thoroughly with water for at least 15 minutes and consult a physician.

**CAUTION: SILVER NITRATE IS A CAUSTIC SUBSTANCE.** Chemical burns may result from inappropriate use of product.

• Wear chemical resistant gloves while using this product. Wear other appropriate personal protective equipment as needed.

- Take care to confine the silver nitrate to the area being treated by using an appropriate physical or chemical barrier to prevent staining or burning of untreated tissue.
- Skin contact time with applicators should be minimal when used on thin delicate skin or neonates.

• Avoid prolonged contact with skin or other surfaces since staining may occur.

#### CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

#### **STORAGE:**

Store in the closed package at room temperature in a dry place protected from light. Silver nitrate will

oxidize and turn dark brown upon exposure to light, however this does not affect the product's potency or utility. Exposure to moisture can cause the tip to break or loosen from the applicator. Store away from vaporous chemicals.

#### **DISPOSAL:**

Expired or unused applicators may be returned for disposal to: GF Health Products, Inc., 33 Plan Way, Bldg. # 2, Warwick, RI 02886, or disposed of according to applicable federal, state and local regulations.

#### PACKAGE LABEL PRINCIPAL DISPLAY PANEL:

2165-100-03	graf <u>co</u>	Item 1590 100 Applicators	NDC 12165-100-03	grafco	Item 1590 100 Applicators
Silver Nitr	Silver Nitrate Applicator - 15 cm (6 inches)		Silver	Silver Nitrate Applicator - 15 cm (6 inches)	
Active Ingredients: Each Silver Nitrate Potassium Nitrate	Active Ingredients: Each Applicator Contains Silver Nitrate		Active I Silver N Potassi	Active Ingredients: Each Applicator Contains Silver Nitrate	
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use of product.

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- Take care to confine the silver nitrate to the area being treated by using an appropriate physical or chemical barrier to prevent staining or burning of untreated tissue.
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## DISPOSAL:

Expired or unused applicators may be returned for disposal to: GF Health Products, Inc. 33 Plan Ways Bidg,  $\pi$ 2, Warwick, El 02886, or disposed of according to applicable foderal, state and local regulations.

CHEMTREC 24-HOUR EMERGENCY TELEPHONE NUMBER: 800-424-9300

Manufactured by: GF Health Products, Inc. Atlants, Georgia 30340 USA www.grahamfield.com

1590-BOX-LAB-RevA20

Made in the UGA

www.grahamfield.com Allanta, GA 30340-3140

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1590-INS-LAB-Rev120

# WARNINGS AND PRECAUTIONS:

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Made in the USA

F Health Products, Inc. Ianta, GA 30340-3140

590-TUBE-LAB-RevA20

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CHEMTREC 24-HOUR EMERGENCY TELEPHONE NUMBER: 800-424-9300

Manufactured by: GF Health Profests. Inc. Atlanta. Georgia 30340 USA www.grahamfield.com

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CHEMTREC 24-HOUR EMERGENCY TELEPHONE NUMBER: 800-424-9300 Manufactured by: GFHealth Products. Inc. Atlanta, Georgia 30140USA www.grahamfield.com

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1590-INS-LAB-Rev120

WARNINGS AND PRECAUTIONS:

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Manufactured by: GFHealth Products, Inc. Atlants, Georgia 30360 USA www.grahambeld.com

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1590-INS-LAB-Rev120

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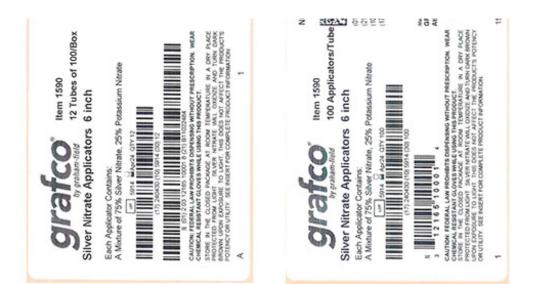






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Product Info	rmation						
Product T ype	e (Source)	ce) NDC:12165-100					
Route of Admin	istration	TOPICAL					
Active Ingred	lient/Active Moi	ety					
Ingredient Name Basis						Strengtl	
SILVER NITRATE (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A) SILVER N						38.21 mg	
				POTASSIUM	DTASSIUM NITRATE 12.74 m		
Inactive Ingr	edients						
Ingredient Name						Strength	
HYDRO CHLORIC ACID (UNII: QTT17582CB)0.036 mg							
SODIUM CHLORIDE (UNII: 451W47IQ8X)							
SODIUM CHLOR	<b>IDE</b> (UNII: 451W47IQ	5A)		(	0.0153 mg		
	<b>IDE</b> (UNII: 451W47IQ	5.7)		(	0.0153 mg		
Packaging	IDE (UNII: 451W47IQ	Package Description		Marketing Sta Date		keting End Date	
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<ul> <li><b>Fractarian</b></li> <li><b>Item Code</b></li> <li>NDC:12165- 100-01</li> </ul>	100 in 1 TUBE; Typ Combined with Drug Information	Package Description 4: Device Coated/Impregnated/Otherwise	e 0	Marketing Sta Date	art Mar	-	

#### **Registrant -** GF Health Products, Inc. (798817599)

Establishment								
Name	Address	ID/FEI	<b>Business Operations</b>					
GF Health Products, Inc.		798817599	manufacture(12165-100)					

Revised: 1/2021

GF Health Products, Inc.