GRAFCO SILVER NITRATE (75% SILVER NITRATE, 25% POTASSIUM NITRATE)- grafco silver nitrate (75% silver nitrate, 25% potassium nitrate) stick
HF Acquisition Co LLC, DBA HealthFirst

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.

GRAFCO SILVER NITRATE 6" APPLICATORS (75% SILVER NITRATE, 25% POTASSIUM NITRATE) 100 PER TUBE

INDICATIONS & USAGE

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

DOSAGE & 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 & 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.

HOW SUPPLIED

NDC 51662-1611-1

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HF Acquisition Co LLC, DBA HealthFirst
11629 49th Pl W.

Mukilteo, WA 98275

PRINCIPAL DISPLAY PANEL - NDC 51662-1611-1

51662-1611-1 Serialized Tube Labeling


grafco
by graham-field
Item 1590
100 Applicators/Tube
NDC12163-100-01
Silver Nitrate Applicators 6 inch
Each Applicator Contains:
A Mixture of 75% Silver Nitrate, 25% Potassium Nitrate
(01)00312165100014
(21)T30265957
(10)6961
(17)240731
Open Th

Tube Labeling

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Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51662-1611(NDC:12165-100)

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	12.74 mg
SILVER NITRATE (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A)	SILVER NITRATE	38.21 mg

Inactive Ingredients

Ingredient Name	Strength
HYDROCHLORIC ACID (UNII: QTT17582CB)	0.036 mg
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0153 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51662-1611-1	100 in 1 TUBE; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug	08/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/10/2022	

Labeler - HF Acquisition Co LLC, DBA HealthFirst (045657305)

Registrant - HF Acquisition Co LLC, DBA HealthFirst (045657305)

Establishment

Name	Address	ID/FEI	Business Operations
HF Acquisition Co LLC, DBA HealthFirst		045657305	relabel(51662-1611)

Revised: 3/2024 HF Acquisition Co LLC, DBA HealthFirst