

STYPTSTIX- silver nitrate applicator stick

Henry Schein Inc.

Reference Label Set Id: 0fff668c-8b5c-4b52-a740-7a078d413620

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.

INDICATIONS AND USAGE:

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.

DOSAGE FORMS AND STRENGTHS:

Stick: 50 mg

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 disposed of according to applicable federal, state and local regulations.

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

HENRY SCHEIN® 112-6994

STYPTSTIX
Silver Nitrate Applicator Sticks
100 Applicators, 6 Inches (15cm)
Each Applicator Contains:
Active Ingredients:
50 mg of a mixture of 75% Silver Nitrate, 25% Potassium Nitrate.

INDICATIONS AND USAGE:
For cauterization of skin or mucous membranes and for removing warts and granulated tissue.

CONTRAINDICATIONS:
Mottled the applicator tip with distilled, deionized or purified water and apply the silver nitrate to the affected area by holding, rubbing, or rolling the tip along the affected tissue. The strength of the action is controlled by the duration with which the applicator tip is held against the tissue. The silver nitrate solution is applied to the skin or mucous membranes by wetting the area with saline solution (0.9% sodium chloride). Using saline solution to wet the applicator tips or residual saline from around 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. Best dry wounds that have been thoroughly washed with saline prior to applying silver nitrate.

DOSSAGE FORMS AND STRENGTHS:
Stick, 50 mg

CONTRAINDICATIONS:
Silver salts stain tissue blue 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.

DOSSAGE FORMS AND STRENGTHS:
Stick, 50 mg

CONTRAINDICATIONS:
Mottled the applicator tip with distilled, deionized or purified water and apply the silver nitrate to the affected area by holding, rubbing, or rolling the tip along the affected tissue. The strength of the action is controlled by the duration with which the applicator tip is held against the tissue. The silver nitrate solution is applied to the skin or mucous membranes by wetting the area with saline solution (0.9% sodium chloride). Using saline solution to wet the applicator tips or residual saline from around 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. Best dry wounds that have been thoroughly washed with saline prior to applying silver nitrate.

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112-6994 (NS) L48 Rev. 07/19

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Each Applicator Contains:
50 mg of a mixture of 75% Silver Nitrate, 25% Potassium Nitrate.

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

INDICATIONS AND USAGE:

Mobilize the applicator tip with distilled, deionized or purified water and apply the silver nitrate to the affected area by nodding, 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 reduce with the action of silver nitrate resulting in cauterization failure. Only use distilled, deionized or purified water to wet applicator tips. Wet dry wounds that have been flushed/washed with saline prior to applying silver nitrate.

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NDC 0041-1000-03

112-6994-NCL-UB-RAC19

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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 the delicate skin of newborns.
• 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.

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HEIN®

112-6994

USE AND PRECAUTIONS:

The active ingredients are poisonous and may be fatal when taken in excessive quantities, which may lead to coma, convulsions, or death. If poisoning occurs, immediately consult a physician. If eye contact, hold eyes open and immediately flush with copious amounts of water. Consult a physician.

WARNING: Chemical burns may result from inappropriate use of this product. Wear other appropriate personal protective equipment as indicated on the label.

If being treated by using an appropriate physical or chemical barrier to prevent when used on the delicate skin or mucous.

Wash skin thoroughly with soap and water.

DO NOT USE:

Do not use on the face, neck, or scalp. Silver nitrate will oxidize hair and does not affect the product's potency or utility.

Keep away from children. Store away from vaporous

DISPOSAL:

Dispose of according to applicable federal, state and local regulations.

Distributed by (in US only):
Henry Schein Inc.
135 Duryea Road
Melville, NY 11747 USA
Mfr. in USA

HEIN®

112-6994

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Melville, NY 11747 USA
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HENRY SCHEIN®

STYPTSTIX

112-6994

16 Boxes/Case

Each Applicator Contains:

50mg of a mixture of 75% Silver Nitrate, 25% Potassium Nitrate

LOT 5650 EXP Jan23 QTY 16



(10) 5650 (17) 230131 (30) 16



N (01) 0 03 04041 00001 3 (21) 100000000383

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. WEAR CHEMICAL-RESISTANT GLOVES WHILE USING THIS PRODUCT.

STORAGE: STORE IN CLOSED PACKAGE AT ROOM TEMPERATURE IN A DRY PLACE AND PROTECTED FROM LIGHT. SILVER NITRATE WILL TURN DARK BROWN UPON EXPOSURE TO LIGHT. THIS DOES NOT AFFECT THE PRODUCTS POTENCY OR UTILITY. SEE INSERT FOR COMPLETE PRODUCT INFORMATION.

NDC 0404-1000-01



(01)00304041000013
(21)100000000383
(10)5650
(17)230131

Distributed by (in US only):

HENRY SCHEIN INC.
135 DURYEA ROAD
MELVILLE, NY 11747 USA

Made in the USA

HS-CASE-LAB-REVA19

A

HENRY SCHEIN®

STYPTSTIX

112-6994

12 Tubes/Box

Each Applicator Contains:

50mg of a mixture of 75% Silver Nitrate, 25% Potassium Nitrate

LOT 5650 EXP Jan23 QTY 12



(10) 5650 (17) 230131 (30) 12



N (01) 0 03 04041 00002 0 (21) 100000006155

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. WEAR CHEMICAL-RESISTANT GLOVES WHILE USING THIS PRODUCT.

STORAGE: STORE IN CLOSED PACKAGE AT ROOM TEMPERATURE IN A DRY PLACE AND PROTECTED FROM LIGHT. SILVER NITRATE WILL TURN DARK BROWN UPON EXPOSURE TO LIGHT. THIS DOES NOT AFFECT THE PRODUCTS POTENCY OR UTILITY. SEE INSERT FOR COMPLETE PRODUCT INFORMATION.

NDC 0404-1000-02



(01)00304041000020
(21)100000006155
(10)5650
(17)230131

Distributed by (in US only):

HENRY SCHEIN INC.
135 DURYEA ROAD
MELVILLE, NY 11747 USA

Made in the USA

HS-BOX-LAB-REVA19

12

A

HENRY SCHEIN®

NDC 0404-1000-03

STYPTSTIX

112-6994

100 Applicators/Tube

Each Applicator Contains:

50mg of a mixture of 75% Silver Nitrate, 25% Potassium Nitrate

LOT 5650 EXP Jan23 QTY 100



(10) 5650 (17) 230131 (30) 100



N (01) 0 03 04041 00003 7 (21) 100000073679



(01)00304041000037

(21)100000073679

(10)5650

(17)230131

Open This End



CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

WEAR CHEMICAL-RESISTANT GLOVES WHILE USING THIS PRODUCT.

STORAGE: STORE IN CLOSED PACKAGE AT ROOM TEMPERATURE IN A DRY PLACE AND PROTECTED FROM LIGHT. SILVER NITRATE WILL TURN DARK BROWN UPON EXPOSURE TO LIGHT. THIS DOES NOT AFFECT THE PRODUCTS POTENCY OR UTILITY. SEE INSERT FOR COMPLETE PRODUCT INFORMATION.

Distributed by (in US only):

HENRY SCHEIN INC.
135 DURYE ROAD
MELVILLE, NY 11747 USA

Made in the USA

HS-TUBE-LAB-REVA19

16

STYPTSTIX

silver nitrate applicator stick

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:0404-1000 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------|----------|
| HYDROCHLORIC ACID (UNII: QTT17582CB) | 0.042 mg |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 0.021 mg |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0404-1000-01 | 16 in 1 CASE | 06/01/2014 | |
| 1 | NDC:0404-1000-02 | 12 in 1 BOX | | |
| 1 | NDC:0404- | 100 in 1 TUBE; Type 4: Device Coated/Impregnated/Otherwise | | |

| | | | |
|------------------------------|---|-----------------------------|---------------------------|
| 1000-03 | Combined with Drug | | |
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved drug other | | 06/01/2014 | |

Labeler - Henry Schein Inc. (012430880)

Revised: 12/2019

Henry Schein Inc.