

REPARA SILVER NITRATE APPLICATORS- silver nitrate stick
PSS World Medical, 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.

REPARA (Silver Nitrate Applicators)

Active Ingredients

Active Ingredients

Each flexible plastic applicator contains:

Silver Nitrate.....75%

Potassium Nitrate.....25%

CAUTION:

Federal (USA) law restricts this device to sale by or on the order of a physician.

DOSAGE & ADMINISTRATION:

Prior to use, the applicator stick may be bent or shaped to allow easier access to the target area. The medicated end of the applicator should be moistened in clean water and applied to the affected tissue. One applicator is normally sufficient for each application. The strength of the action is controlled by the amount of water used to moisten the tip. The applicator action can be stopped by washing the area with a saline solution (0.9% sodium chloride).

USES:

Repara® Silver Nitrate Applicators are useful for cauterization of skin or mucous membrane and for the removal of granulation tissue, warts and verrucae.

CONTRAINDICATIONS & ANTIDOTES:

Repara® Silver Nitrate Applicators must not be used for genital warts. Continued application to mucous membranes and open wounds leads to argyria, a bluish-black discoloration of the skin due to depositions of granules of silver compounds in the connective tissues. This condition persists indefinitely or disappears very slowly. Poisoning by oral ingestion is unlikely with the quantities involved, but treatment for poisoning is the immediate ingestion of large amounts of salt water followed by an emetic. Then administer a dose of Epsom salts followed with milk. Immediately call a physician.

CAUTION:

KEEP OUT OF REACH OF CHILDREN. DO NOT USE ON OR NEAR EYES.

STORAGE:

Store at room temperature in the closed package, in a dry place protected from light. Exposure to light will cause the silver nitrate tip to turn black, but will not affect the product's potency.

Comment or Questions?

Call (800) 777-4908

Manufacturing Information

Made in England

Manufactured for PSS World Medical, Inc.

4345 Southpoint Blvd.

Jacksonville, FL 32216

Package Label

1655 Each

NDC 68345-100-60

SILVER NITRATE APPLICATORS

6 in.

- Flexible plastic applicator containing 75% Silver Nitrate and 25% Potassium Nitrate

100 each/vial

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Comments or Questions? 800-777-4908 | Made in England | Rev.00 09/2012



LOT



Reorder # 1655



+M34016553

1655 Case

NDC 68345-100-60



1655

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100 each/vial, 10 vials/box, 10 boxes/case



+M34016551

PO #

NW:

GW:

Carton #:

LOT



Reorder # 1655

1655 Box

NDC 68345-100-60



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REPARA SILVER NITRATE APPLICATORS

silver nitrate stick

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:68345-100 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| SILVER NITRATE (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A) | SILVER NITRATE | 75 mg |
| POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844) | POTASSIUM NITRATE | 25 mg |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:68345-100-60 | 10 in 1 CASE | | |
| 1 | | 10 in 1 BOX | | |
| 1 | | 100 in 1 VIAL | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| unapproved drug other | | 10/26/2012 | |

Labeler - PSS World Medical, Inc. (101822682)**Registrant** - PSS World Medical, Inc. (101822682)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|--------------------|----------------|---------------|----------------------------|
| Bray Group Limited | | 217504463 | manufacture(68345-100) |

Revised: 10/2012

PSS World Medical, Inc.