

APLICARE POVIDONE-IODINE TRIPLES- povidone-iodine solution
Aplicare Products, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

5101 Aplicare Povidone-iodine Triples

Active ingredient

Povidone-iodine USP 10%

Purpose

Antiseptic

Use

antiseptic skin preparation

Warnings

- **For external use only**
- **Avoid pooling beneath patient**

Do not use

- • if allergic to iodine
- • in the eyes

Ask a doctor before use if injuries are

- • deep or puncture wounds
- • serious burns

Stop use and ask a doctor if

- • redness, irritation, swelling or pain persists or increases
- • infection occurs

Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.

Storage Information

Avoid excessive heat. Store at room temperature.

Directions

- apply locally as needed

Other information

- • 1% titratable iodine
- • not made with natural rubber latex
- • for hospital or professional use only
- • for single use only

Inactive ingredients

citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water

Manufacturing Information

Manufactured by:

Aplicare Products, LLC

550 Research Parkway, Meriden, CT 06450 USA

Manufactured for:

Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

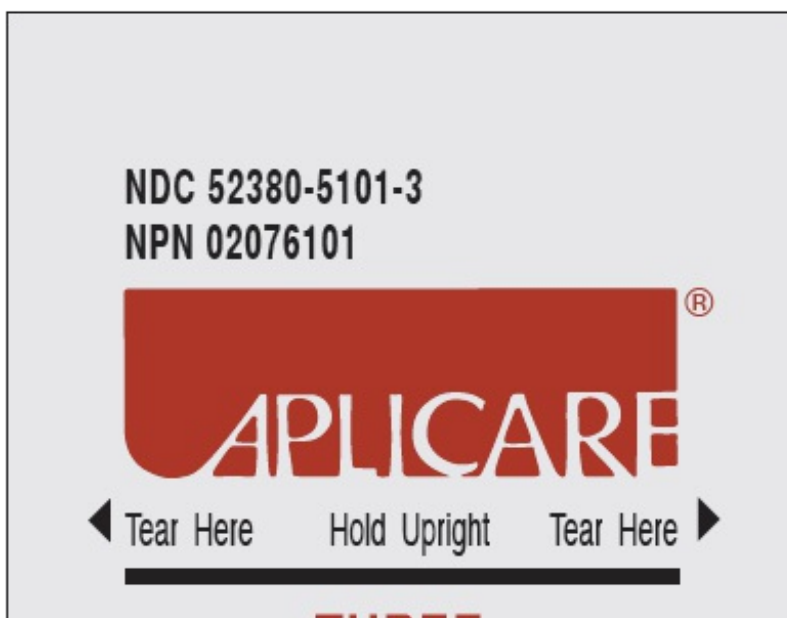
Made in USA with domestic and foreign materials

1-800-633-5463

REF: APLS3111

0117

Package Label



THREE POVIDONE-IODINE SWABSTICKS

ANTISEPTIC
Non-Sterile Solution

Three 4-inch Saturated Swabsticks

Drug Facts

| <i>Active Ingredient</i> | <i>Purpose</i> |
|------------------------------|----------------|
| Povidone-iodine USP 10%..... | Antiseptic |

Use antiseptic skin preparation

Warnings

Do not use ■ if allergic to iodine ■ in the eyes

For external use only ▶

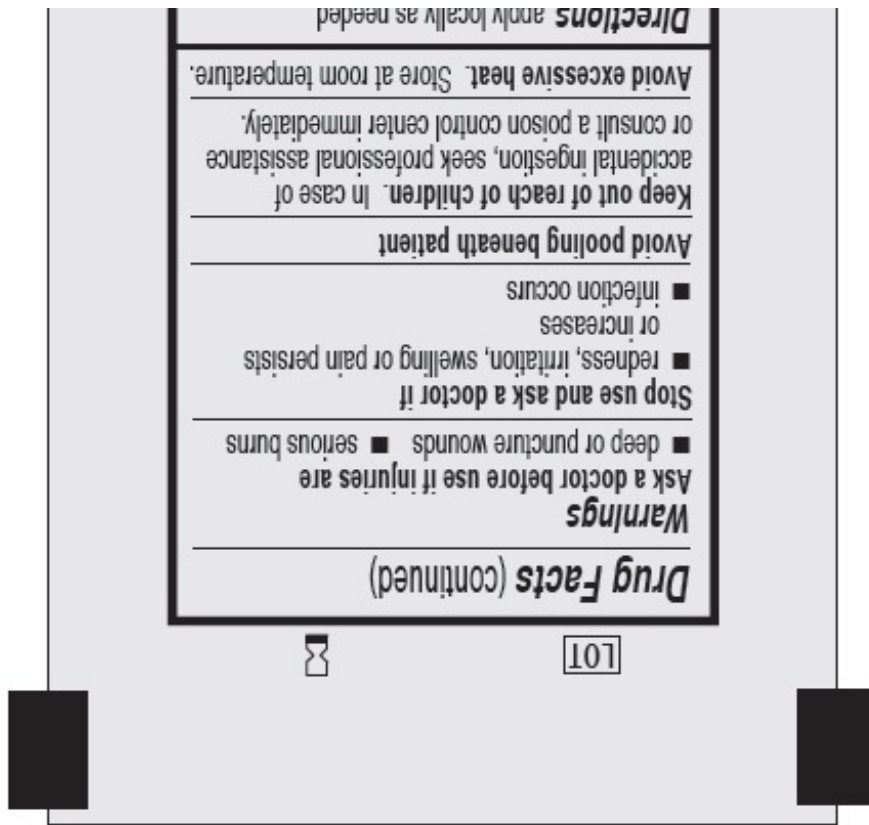
Reorder No. S-3111

For questions, comments, or to report
serious side effects:
☎ 800-760-3236
Monday-Friday 8:30 a.m.-5:00 p.m. EST
APPLICARE, INC.
MERIDEN, CT 06450 U.S.A.
BRAMPTON, ON L6W 4V3 CANADA
www.applicare.com
0117

(01)00352380510137

Inactive ingredients
citric acid, disodium phosphate, nonoxonyl-9,
sodium hydroxide, water

Other information
■ 1% titratable iodine
■ not made with natural rubber latex
■ for hospital or professional use only
■ for single use only



APPLICARE POVIDONE-IODINE TRIPLES

povidone-iodine solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52380-5101 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4) | IODINE | 10 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| NONOXYNOL-9 (UNII: 48Q180SH9T) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
| | | | | |

| | | | | |
|---|------------------|---|------------|------------|
| 1 | NDC:52380-5101-3 | 6.5 mL in 1 PACKET; Type 0: Not a Combination Product | 05/31/2017 | 11/30/2025 |
| 2 | NDC:52380-5101-2 | 25 in 1 BOX | 05/31/2017 | 11/30/2025 |
| 2 | | 6.5 mL in 1 PACKET; Type 0: Not a Combination Product | | |
| 3 | NDC:52380-5101-1 | 250 in 1 CASE | 05/31/2017 | 11/30/2025 |
| 3 | | 6.5 mL in 1 PACKET; Type 0: Not a Combination Product | | |
| 4 | NDC:52380-5101-5 | 500 in 1 CASE | 05/31/2017 | 11/30/2025 |
| 4 | | 6.5 mL in 1 PACKET; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 05/31/2017 | 11/30/2025 |

Labeler - Aplicare Products, LLC (081054904)

Registrant - Medline Industries, LP (025460908)

Revised: 8/2023

Aplicare Products, LLC