

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.

3101 Aplicare Povidone-iodine Triples

Active ingredient

Povidone-iodine 10%

(equivalent to 1% available iodine)

Purpose

Antiseptic

Use

antiseptic skin preparation

Warnings

- **For external use only**
- **Avoid pooling beneath patient**
- **Avoid excessive heat. Store at room temperature.**

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

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

Keep out of reach of children.

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

Directions

- apply locally as needed

Other information

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

Inactive ingredients

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

Manufacturing Information

Manufactured for:

Medline industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

Manufactured by:

Aplicare Products, LLC

550 Research Parkway, Merident, CT 06450 USA

1-800-633-5463

REF: APLS31015S

Package Label

NDC 52380-3101-5



◀ Tear Here Hold Upright Tear Here ▶

THREE
POVIDONE-IODINE
SWABSTICKS
ANTISEPTIC
STERILE Solution
Applicator is STERILE if Package
is Intact

Three 4-inch Saturated Swabsticks

STERILE SOLUTION

<i>Drug Facts</i>	
<i>Active ingredient</i>	<i>Purpose</i>
Povidone-iodine USP 10%.....	Antiseptic
<i>Use</i> antiseptic skin preparation ▶	

Reorder No. S-3101

For questions, comments, or to report serious side effects:
1-800-MEDLINE ☎
 Monday-Friday 8:30 a.m.-5:00 p.m. EST
 Manufactured by:
 Medline Industries, Inc.
 Northfield, IL 60093 U.S.A.
 www.medline.com
 Aplicare is a registered trademark of
 Medline Industries, Inc.
 0917

(01) 0 0352380 31015 7



Drug Facts (continued)

Warnings

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

For external use only

Ask a doctor before use if injuries are

- deep or puncture wounds
- serious burns

Stop use and ask a doctor if

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

Avoid pooling beneath patient

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

Avoid excessive heat. Store at room temperature.

Directions apply locally as needed

Other information

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

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



LOT

APLICARE POVIDONE-IODINE TRIPLES

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52380-3101
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:52380-3101-5	6.5 mL in 1 PACKET; Type 0: Not a Combination Product	03/01/1998	03/31/2025
2	NDC:52380-3101-1	500 in 1 CASE	03/01/1998	03/31/2025
2		6.5 mL in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:52380-3101-2	25 in 1 BOX	03/01/1998	02/28/2019
3		6.5 mL in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:52380-3101-3	250 in 1 CASE	03/01/1998	02/28/2019
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	03/01/1998	03/31/2025

Labeler - Aplicare Products, LLC (081054904)**Registrant** - Medline Industries, LP (025460908)