# APLICARE POVIDONE-IODINE PAINT- povidone-iodine solution Aplicare, Inc.

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.

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#### **Aplicare Povidone-Iodine Paint**

Drug Facts

#### Active ingredient

Povidone-iodine USP 10%

#### Purpose

Antiseptic

#### Use

antiseptic skin preparation

#### Warnings

#### Do not use

- if allergic to iodine
- in the eyes

#### Ask a doctor before use if injuries are

- deep wounds
- puncture wounds
- serious burns

#### Stop use and ask a doctor if

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

#### For external use only

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

Avoid pooling beneath the patient. Prolonged exposure to wet solution may cause skin irritation.

Avoid excessive heat. Store at room temperature.

#### Directions

use sponge sticks to prep desired area

#### 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

For questions, comments, or to report serious side effects:

#### 800-760-3236

Monday-Friday 8:30 a.m.-5:00 p.m. EST

### **PRINCIPAL DISPLAY PANEL - 2 Sponge Sticks Packet**

#### NDC 52380-4011-2

#### APLICARE

□ Tear Here Hold Upright Tear Here □

# TWO POVIDONE-IODINE PAINT SPONGE STICKS

#### ANTISEPTIC Non-Sterile Solution

Two 8-inch Sponge Sticks Saturated with Povidone-Iodine USP, 1% Available Iodine

Reorder No. F-2011

### NDC 52380-4011-2

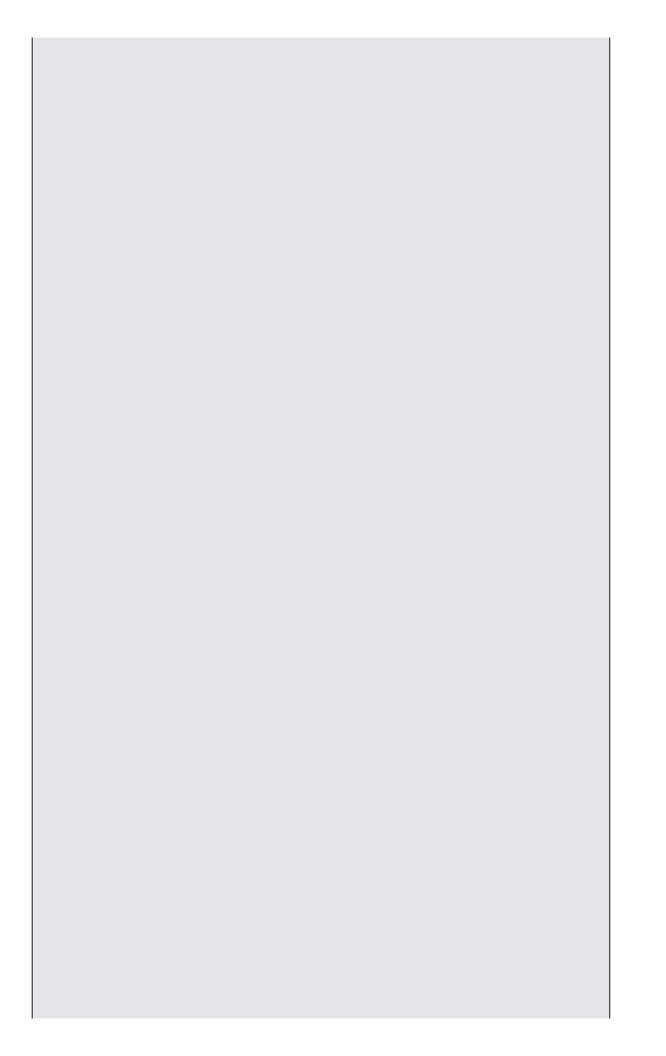


# **TWO POVIDONE-IODINE PAINT** SPONGE STICKS

## ANTISEPTIC **Non-Sterile Solution**

Two 8-inch Sponge Sticks Saturated with Povidone-Iodine USP, 1% Available Iodine

Drug Facts	Drug Facts (continued)				
Active ingredient Purpose Povidone lotine USP 10%Antiseptic	Warnings Avoid excessive heat. Store at room temperature.				
Use antiseptic skin preparation	Directions use sponge sticks to prepdesired area				
Warnings Donotuse a it alengic to iodine a in the eyes	Other information = 1% itratable iodine = for single use only = notmade with natural rubber latex = for hospital or professional use only Inacti ve Ingredients citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water				
Ask a doctor before use if injuries are deep wounds puncture wounds serious burns					
Stop use and ask a doctor lif redness, initiation, swelling or pain persists or increases infection occurs	For questions, comments, or to report serious side effects <b>0</b> 800-760-3236 Monday-Friday 8:30 a.m5:00 p.m. EST				
For external use only	APLICARE, INC.				
Keep out of reach of children. In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.	APLICARE, INC. MERIDEN, CT 06450 U.S.A. www.aplicare.com 0117 Reorder No. F-2011				
Avoid pooling beneath the patient. Prolonged exposure to wet solution may cause skin irritation.					



### APLICARE POVIDONE-IODINE PAINT

povidone-iodine solution

Rotative Type       TOPICAL         Restance of Administration         TOPICAL         Active Ingredient/Active Moiety         Ingredient Name         Basis of Strength         Streng		1011							
TOPICAL         Active Ingredient/Active Moiety         Basis of Strength       Strength         OVIDONE-IO DINE (UNIE 85H0 HZU39 M) (IO DINE - UNIE9679TC07X4)       IO DINE       IO mg         Ingredient Name       Basis of Strength       Strength         Ingredient Name       Strength         CITRIC ACID MONOHYDRATE (UNIE 2968PHW8QP)       Strength         SODIUM PHO SPHATE, DIBASIC (UNIE: 2968PHW8QP)       Strength         SODIUM HYDRO XIDE (UNIE: 5504QC32)       Strength         NONOXYNOL-9 (UNIE: 4801805H9T)       Strength         Varter (UNIE: 0590F0K00R)       Strength         Solum HYDRO XIDE (UNIE: 5504QC32)         NONOXYNOL-9 (UNIE: 4801805H9T)       Strength         Varter (UNIE: 0590F0K00R)       Strength         Varter (UNIE: 0590F0K00R)       Strength         Solum HYDRO XIDE (UNIE: 552380-4011-2)       Strength         Varter (UNIE: 0590F0K00R)       Strength         Varter (UNIE: 0590F0K00R)       Strength         Solum HYDRO XIDE (UNIE: 552380-4011-2)       Strength         Varter (UNIE: 052380-4011-2)       2 mL in 1 PACKET; Type 0: Not a Combination Product)	duct Informatio	on							
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SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I) Image: Solution of the state of the s									
NOXYNOL-9 (UNII: 48/1805H9T)   WATER (UNII: 059QF0K00K   Packaging   Item Code   Package Description   Marketing Start Date   Marketing Information Product   Starketing Information Number or Monograph Citation   Marketing Start Date   Marketing Start Date	SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)								
WATER (UNII: 059QF0UUU: 059QF0UUUU: 059QF0UUUUUUUUUUUUUUUUUUUUUUUUUUUUUUUUUUUU	SO DIUM HYDRO XIDE (UNII: 55X04QC32I)								
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Labeler - Aplicare, Inc. (107255002)

Establishment						
Name	Address	ID/FEI	<b>Business Operations</b>			
Aplicare, Inc.		107255002	manufacture(52380-4011)			

Revised: 6/2017

Aplicare, Inc.