

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.

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



◀ Tear Here Hold Upright Tear Here ▶

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Drug Facts (continued)
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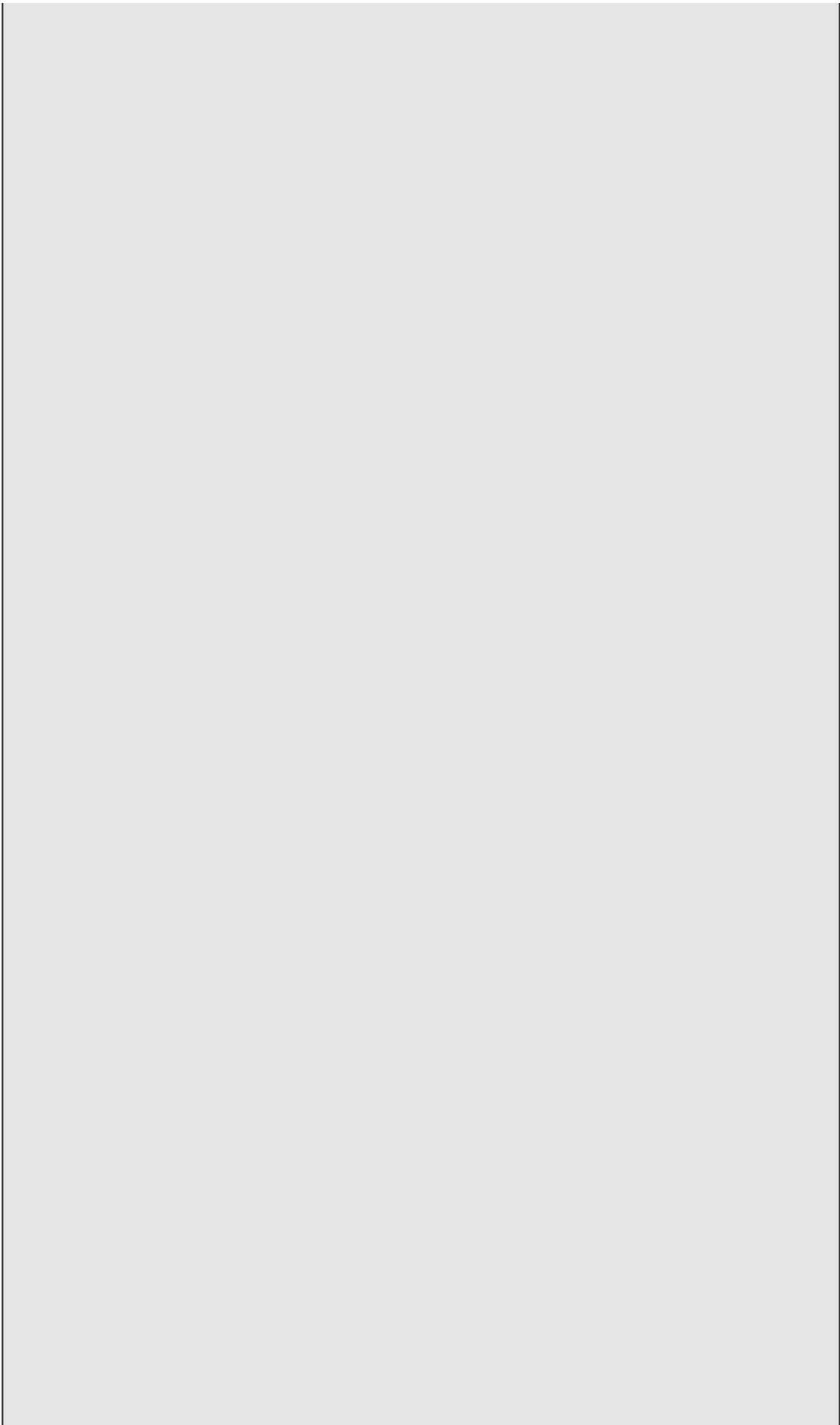
☎ 800-760-3236

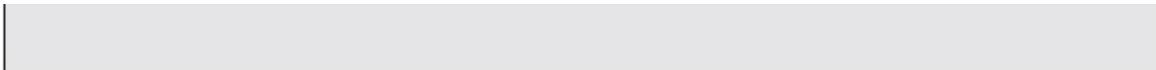
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0117

Reorder No. F-2011







APLICARE POVIDONE-IODINE PAINT

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52380-4011
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-4011-2	2 mL in 1 PACKET; Type 0: Not a Combination Product	05/31/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/31/2017	

Labeler - Aplicare, Inc. (107255002)

Establishment

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