APLICARE POVIDONE-IODINE PREP PAD- 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 Prep Pad

Active Ingredient

Povidone-iodine USP 10%

Purpose

Antiseptic

Use

antiseptic skin preparation

Directions

Apply locally as needed.

Other Information

- Prep pad size: 1-1/4" × 1-1/2"
- 1% titratable iodine
- Not made with natural rubber latex
- For hospital or professional use only

Inactive ingredients

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

Warnings

- **Do not use** if allergic to iodine or in the eyes
- **For external use only**
- **Ask a doctor before use** if injuries are deep wounds, puncture wounds, or serious burns
- **Stop use and ask a doctor** if infection occurs or if 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.
- **Avoid excessive heat.** Store at room temperature.

PRINCIPAL DISPLAY PANEL - 10 mg Pad Packet

APLICARE

NDC 52380-4111-1

POVIDONE-IODINE PREP PAD

ANTISEPTIC / Non-Sterile Solution

Reorder No. APLP1111

APLICARE®

NDC 52380-4111-2

POVIDONE-IODINE PREP PAD

ANTISEPTIC / Non-Sterile Solution

Active Ingredient	Purpose
Povidone-iodine USP 10%	Antiseptic

Directions Apply locally as needed.

Other Information
- Prep pad size: 1-1/4" x 1-1/2"
- 1% titratable iodine
- Not made with natural rubber latex
- For hospital or professional use only

Reorder No. APLP1111

Warnings ■ For external use only ■ Do not use if allergic to iodine or in the eyes ■ Ask a doctor before use if injuries are deep wounds, puncture wounds, or serious burns ■ Stop use and ask a doctor if infection occurs or if 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. ■ Avoid excessive heat. Store at room temperature.

See Drug Facts for Full Disclosure

(01)00352380411120

Manufactured by: Medline Industries, Inc.
Northfield, IL 60093 U.S.A. RF18APL

Tear Here LOT Tear Here

APLICARE POVIDONE-IODINE PREP PAD

povidone-iodine solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52380-4111
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)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52380-4111-1	0.5 mL in 1 PACKET; Type 0: Not a Combination Product	05/31/2017	
2	NDC:52380-4111-2	0.5 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. (081054904)

Establishment

Name	Address	ID/FEI	Business Operations
Aplicare Products, LLC		081054904	manufacture(52380-4111)

Revised: 12/2019 Aplicare, Inc.