APLICARE POVIDONE-IODINE- povidone-iodine ointment
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.

Aplicare Povidone-Iodine

Active Ingredient

Povidone-iodine USP 10%

Purpose

Antiseptic

Use

antiseptic skin preparation

Directions

Apply locally as needed.

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.

Other Information

- 1% titratable iodine
- Not made with natural rubber latex
- For hospital or professional use only

Inactive ingredients

glycerin, polyethylene glycol, propylene glycol

PRINCIPAL DISPLAY PANEL - 1 gram Ointment Packet

NDC 52380-0126-2

NPN 02076071

*A*PLICARE

POVIDONE-IODINE
OINTMENT

ANTISEPTIC/Non-Sterile Solution

Net Wt. 1 gram

LOT

NDC 52380-0126-2 NPN 02076071

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LOT

Tear Here ◀ Tear Here ▶

See Drug Facts for Full Disclosure

Warnings ■ **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. ***Other Information*** ■ 1% titratable iodine ■ Not made with natural rubber latex ■ For hospital or professional use only

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BRAMPTON, ON L6W 4V3 CANADA
www.aplicare.com 0117

Reorder No. L-2011

APLICARE POVIDONE-IODINE

povidone-iodine ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52380-0126
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 g

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52380-0126-2	1 g 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 Products, LLC (081054904)

Establishment

Name	Address	ID/FEI	Business Operations
Aplicare Products, LLC		081054904	manufacture(52380-0126)

Revised: 2/2019 Aplicare Products, LLC