APLICARE POVIDONE-IODINE- povidone-iodine solution Aplicare Products, LLC

0011 Povidone-Iodine (nonsterile)

Active ingredient

Povidone-iodine USP 10%

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

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

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

- 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 by:
Aplicare Products, LLC.
550 Research Parkway, Meriden, CT 06450
Made in USA
1-800-633-5463
0117

Package Label

NDC 52380-0011-1 NPN 02076144





ONE FLUID OUNCE POVIDONE-IODINE SOLUTION

ANTISEPTIC Non-Sterile Solution

1 Fl. oz. (30 mL)

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
For external use only	>

Reorder No. L-1011

Drug Facts (continued)

Warnings

Ask a doctor before use if injuries are

deep or puncture wounds serious burns

Stop use and ask a doctor if

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

Avoid pooling beneath patient

Avoid excessive heat. Store at room temperature.

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
- not made with natural rubber latex
- for hospital or professional use only

/nactive ingredients citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water



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

3 800-760-3236

Monday-Friday 8:30 a.m.-5:00 p.m. EST APLICARE, INC. MERIDEN, CT 06450 U.S.A. BRAMPTON, ON L6W 4V3 CANADA www.aplicare.com 0117 NDC 52380-0011-3 NPN 02076144





3/4 FLUID OUNCE POVIDONE-IODINE SOLUTION

ANTISEPTIC Non-Sterile Solution

0.75 Fl. oz. (22.5 mL)

Drug Facts	
Active ingredient Povidone-iodine USP 10%	Purpose Antiseptic
Use antiseptic skin preparation	37/
Warnings Do not use ■ if allergic to iodine ■	■ in the eyes
For external use only)

Reorder No. L-3011

Drug Facts (continued)

Warnings

Ask a doctor before use if injuries are

deep or puncture wounds serious burns

Stop use and ask a doctor if

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

Avoid pooling beneath patient

Avoid excessive heat. Store at room temperature.

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
- not made with natural rubber latex
- for hospital or professional use only

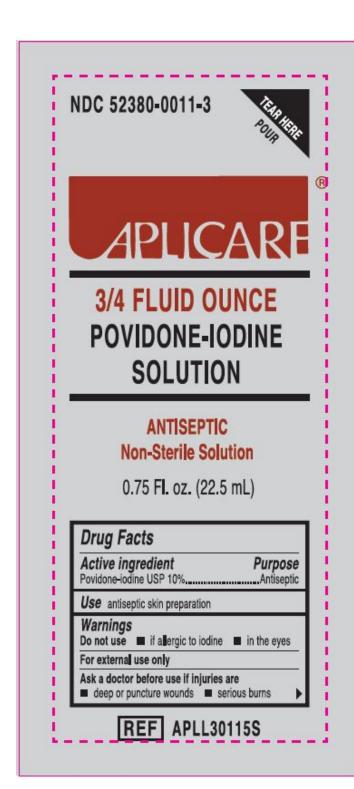
/nactive ingredients citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water

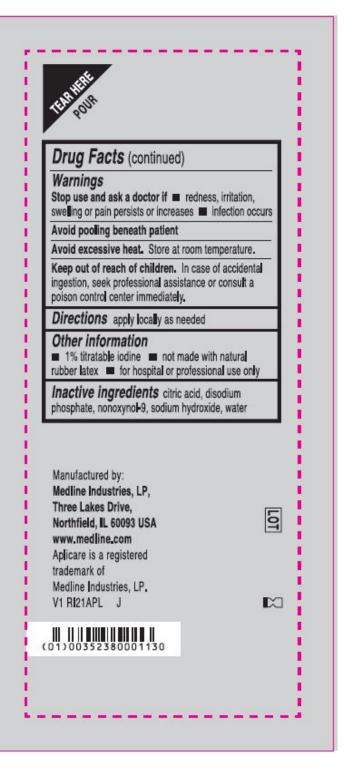


For questions, comments, or to report serious side effects:

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APLICARE POVIDONE-IODINE

povidone-iodine solution

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:52380-0011 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)		
NONOXYNOL-9 (UNII: 48Q180SH9T)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
WATER (UNII: 059QF0KO0R)		

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380- 0011-1	30 mL in 1 PACKET; Type 0: Not a Combination Product	05/31/2017	11/30/2025
2	NDC:52380- 0011-3	22.5 mL in 1 PACKET; Type 0: Not a Combination Product	05/31/2017	09/30/2026

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003	05/31/2017	09/30/2026

Labeler - Aplicare Products, LLC (081054904)

Registrant - Medline Industries, LP (025460908)

Revised: 10/2023 Aplicare Products, LLC