

APLICARE POVIDONE-IODINE- povidone-iodine solution

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.

0001 Povidone-Iodine Pouch (sterile)

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 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 USA

Made in USA

1-800-633-5463

0917

Package Label

NDC 52380-0001-3



3/4 FLUID OUNCE
POVIDONE-IODINE
SOLUTION

ANTISEPTIC
STERILE Solution

0.75 Fl. oz. (22.5 mL)

STERILE SOLUTION

<i>Drug Facts</i>	
<i>Active ingredient</i>	<i>Purpose</i>
Povidone-iodine USP 10%.....	Antiseptic
<i>Use</i> antiseptic skin preparation ▶	

Reorder No. L-3001

TEAR HERE
POUR

LOT



Drug Facts (continued)

Warnings

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(01) 0 0352380 00013 3

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

☎ **1-800-MEDLINE**

Monday-Friday 9:30 a.m.-5:00 p.m. EST

Manufactured by:

Medline Industries, Inc.

Northfield, IL 60092 U.S.A.

www.medline.com

Aplicare is a registered trademark of
Medline Industries, Inc.

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NDC 52380-0001-3

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POUR



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ANTISEPTIC
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STERILE SOLUTION

Drug Facts

Active ingredient	Purpose
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Use antiseptic skin preparation

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REF APLL30015S

TEAR HERE
POUR

Drug Facts (continued)

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Other information ■ 1% titratable iodine

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

Inactive ingredients citric acid, disodium phosphate, nonoxonyl-9, sodium hydroxide, water

Manufactured by:

Medline Industries, LP,

Three Lakes Drive,

Northfield, IL 60093 USA

www.medline.com

1-800-MEDLINE

Aplicare is a registered trademark
of Medline Industries, LP.

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LOT



(01) 0 0352380 00013 3

APLICARE POVIDONE-IODINE

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52380-0001
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)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-0001-1	30 mL in 1 PACKET; Type 0: Not a Combination Product	02/15/2018	03/31/2020
2	NDC:52380-0001-3	22.5 mL in 1 PACKET; Type 0: Not a Combination Product	02/15/2018	05/31/2025
3	NDC:52380-0001-5	0.5 mL in 1 PACKET; Type 0: Not a Combination Product	02/15/2018	07/01/2021
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	03/01/1984	05/31/2025

Labeler - Aplicare Products, LLC (081054904)

Registrant - Medline Industries, LP (025460908)

Revised: 12/2022

Aplicare Products, LLC