

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

2801Aplicare Povidone Iodine Solution

Active ingredient

Povidone-iodine 10%
(equivalent to 1% available iodine)

Purpose

Antiseptic

Use

- • antiseptic skin preparation
- • single use when used for patient preoperative skin preparation

Warnings

- **For external use only**
- **Avoid "pooling" beneath patient. Prolonged exposure to wet solution may cause skin irritation.**

Do not use

- • in the eyes
- • on individuals allergic or sensitive to iodine

Ask a doctor before use if injuries are

- • deep or puncture wounds
- • serious burns

Stop use and ask a doctor if

- • infection occurs
- • 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.

Directions

- apply locally as needed

Other information

- 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 Way, Meriden, CT 06450 USA

Made in USA

REF: APL82342K

RL17HND

Package Label

APPLICARE[®]

NDC 52380-2801-8 REF APL82342K

10% POVIDONE-IODINE SOLUTION

ANTISEPTIC

NON-STERILE SOLUTION

2 Fl. Oz. (59 mL)

Manufactured By:
APPLICARE PRODUCTS, LLC
550 Research Parkway
Meriden, CT 06450 USA
Made in USA RL17HND

(01)00352380280184

Drug Facts

Active ingredient	Purpose
Povidone-iodine 10%..... (equivalent to 1% available iodine)	Antiseptic

Use

- antiseptic skin preparation
- single use when used for patient preoperative skin preparation

Drug Facts, cont.

Warnings
For external use only

Do not use ■ in the eyes ■ on individuals allergic or sensitive to iodine

Ask a doctor before use if injuries are

- deep or puncture wounds
- serious burns

Stop use and ask a doctor if ■ infection occurs

- redness, irritation, swelling or pain persists or increases

Avoid "pooling" beneath patient. Prolonged exposure to wet solution may cause skin irritation.

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.

Directions apply topically as needed

Other information ■ Not made with natural rubber latex

- for hospital or professional use only

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

Questions or comments?
☎ 1-800-633-5463

APPLICARE POVIDONE-IODINE

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52380-2801
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:52380-2801-8	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/1998	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	01/01/1998	

Labeler - Apicare Products, LLC (081054904)**Registrant** - Medline Industries, LP (025460908)