

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.

Aplicare Non-Sterile Povidone-iodine Prep Swabs, 10%

Povidone-iodine USP 10%

Antiseptic

- antiseptic skin preparation
- single use when used for patient preoperative skin preparation and/or preinjection indication

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

For external use only.

Do not use

- in the eye
- on individuals allergic or sensitive to iodine

Ask 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.

- Reverse cardboard sleeve then crush at dot between thumb and forefinger
- Allow solution to saturate tip
- apply topically as needed

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

Other information

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

Questions or comments?

1 800 633 5463

APLICARE

POVIDONE-IODINE PREP SWABS

ANTISEPTIC

NON-STERILE SOLUTION



NDC 52380-1721-1

10% POVIDONE IODINE PREP SWABS

ANTISEPTIC NON-STERILE SOLUTION
100 INDIVIDUAL APPLICATIONS

APL82278
RJ18J-A

APLICARE PRODUCTS, LLC
550 RESEARCH PARKWAY
MERIDEN, CT 06450 USA MADE IN USA



Drug Facts

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

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

Drug Facts (continued)

Warnings

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

Directions ■ Reverse cardboard sleeve then crush at dot between thumb and forefinger ■ Allow solution to saturate tip ■ apply topically as needed

Other information ■ Not made with natural rubber latex ■ for hospital or professional use only

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

Questions or comments?

1-800-633-5463

APLICARE® NDC 52380-1721-1
APL82278

Prep Swab, 0.65 cc
Povidone Iodine Solution, 10%
ANTISEPTIC
NON-STERILE SOLUTION
See Drug Facts For Full Disclosure

Reverse Cardboard Sleeve Then Crush

At Dot Between Thumb & Forefinger

Aplicare Products, LLC, Meriden, CT 06450, USA (RJ18J-A)
Lot No. XXXXX Exp. XXXXX

APLICARE POVIDONE-IODINE

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52380-1721
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
NONOXYNOL-10 (UNII: K7O76887AP)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-1721-1	0.65 mL in 1 PACKET; Type 0: Not a Combination Product	09/01/1998	11/06/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/01/1998	11/06/2022

Labeler - Aplicare Products, LLC. (081054904)

Establishment

Name	Address	ID/FEI	Business Operations
Aplicare Products, LLC.		081054904	manufacture(52380-1721)

Revised: 12/2019

Aplicare Products, LLC.