

APLICARE POVIDONE IODINE- povidone iodine gel
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 Gel, 10%

Povidone-iodine USP 10%

Antiseptic

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

Do not use if allergic to iodine

For external use only

Do not use in eyes

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

Stop use and ask a doctor if

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

Ask a doctor before use if injuries are

- deep or puncture wounds
- serious burns

Questions or comments?

1-800-760-3236 (Mon to Fri 8:30 AM - 5:00 PM EST)

Use

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

Directions apply locally as needed.

Other information

- 1% titratable iodine
- latex free
- for professional or professional use only
- disodium phosphate
- glycerin
- hydroxyethylcellulose
- nonoxynol-10
- simethicone
- water


APLICARE

POVIDONE-IODINE GEL

ANTISEPTIC

NON-STERILE SOLUTION

APLICARE, INC.
Meriden, CT 06450-7172
www.aplicare.com
Made in U.S.A.
L269-1014



NDC 52380-1738-4 Reorder No. 82-269

**POVIDONE-IODINE
GEL**
ANTISEPTIC
NON-STERILE SOLUTION

4 Fl. Oz. (118 mL)

Drug Facts, cont.

Warnings
Do not use if allergic to iodine

For external use only

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
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Do not use in eyes

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 locally as needed

Other information

- 1% titratable iodine ■ latex free
- for hospital or professional use only

Inactive ingredients disodium phosphate, glycerin, hydroxyethylcellulose, nonoxynol-10, simethicone, water

Questions or comments?
☎ 1 800 760-3236 (Mon - Fri 8:30 AM - 5:00 PM EST)



(01)00352380173844

Drug Facts

Active ingredient	Purpose
Povidone-iodine USP 10%.....	Antiseptic

Use ■ antiseptic skin preparation ■ single use
when used for patient preoperative skin preparation and/or preinjection indications ▶

APLICARE POVIDONE IODINE

povidone iodine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52380-1738
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0 HZU99M) (IODINE - UNII:9679 TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
NONOXYNOL-10 (UNII: K7O76887AP)	

GLYCERIN (UNII: PDC6A3C0OX)

WATER (UNII: 059QF0K00R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-1738-4	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/1998	11/06/2022
2	NDC:52380-1738-5	118 mL in 1 BOTTLE; 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
Ashland Chemical (ISP Chemicals LLC)		002188894	api manufacture(52380-1738)

Establishment

Name	Address	ID/FEI	Business Operations
Medline (Hartland)		079800021	manufacture(52380-1738)

Establishment

Name	Address	ID/FEI	Business Operations
Aplicare Products, LLC.		081054904	manufacture(52380-1738) , repack(52380-1738)

Revised: 11/2019

Aplicare Products, LLC.