APLICARE- povidone-iodine solution
Aplicare Products, LLC

0012 Aplicare Povidone-Iodine Solution (non-sterile)

Active Ingredient

Povidone-iodine USP 10% w/v

Purpose

Antiseptic

Uses

- for preparation of the skin prior to surgery
- helps reduce bacteria that potentially can cause skin infection

Warnings

For external use only

Do not use

- if allergic to iodine
- in the eyes or apply over large areas of the body
- in case of deep or puncture wounds, animals bites, or serious burns, consult a doctor

Discontinue use if

- irritation and redness develop.
- If condition persists for more than 72 hours consult a doctor

Avoid pooling beneath patient

Keep out of reach of children.

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

Directions

antiseptic skin preparation: apply locally as needed.

Other information

- 1% titratable iodine
- not made with natural rubber latex

- for hospital or professional use only
- protect from freezing, avoid excessive heat
- store at room temperature

Inactive ingredients

alkyl glucoside, citric acid, glycerin, hydroxyethyl cellulose, nonoxynol-10, potassium iodide, purified water, sodium hydroxide

Manufacturing information

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Manufactured for Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

1-800-MEDLINE Made in China. V1 RL24CZU

Package Label

APLICARE

povidone-iodine solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52380-0012
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**
C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
NONOXYNOL-10 (UNII: K7O76887AP)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID (UNII: 2968PHW8QP)	
POTASSIUM IODIDE (UNII: 1C4QK22F9J)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-0012-3	22.5 mL in 1 PACKET; Type 0: Not a Combination Product	12/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	12/01/2024	

Labeler - Aplicare Products, LLC (081054904)

Registrant - Medline Industries, LP (025460908)

Revised: 12/2024 Aplicare Products, LLC