APLICARE POVIDONE-IODINE PAINT- 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.

0101 Aplicare Povidone-Iodine Paint

Active ingredient

Povidone-iodine USP 10%

Purpose

Antiseptic

Use

antiseptic skin preparation

Warnings

For external use only

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

Avoid excessive heat. Store at room temperature.

Do not use

- if allergic to iodine
- in the eyes

Ask a doctor before use if injuries are

- deep wounds
- 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

use sponge sticks to prep desired area

Other information

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

Inactive ingredients

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

Package Label



Two 8-inch Sponge Sticks Saturated with

STERILE SOLUTION

Drug Facts

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Drug Facts (continued)

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Inactive ingredients ditricacid, disodium phosphate, nonoxynol-9, sodium hydroxide, water

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

(D) 1-800-633-5463

Manufactured by: Aplicare Products, LLC Meriden, CT 06450 www.medline.com

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Reorder No. ORF20015S



APLICARE POVIDONE-IODINE PAINT

povidone-iodine solution

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HUMAN OTC DRUG Item Code (Source) NDC:52380-0101 **Product Type**

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

SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

F	Packaging						
#	tem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:52380- 0101-5	2 in 1 PACKAGE	03/01/1992	07/31/2025			
1		52.5 mL in 1 APPLICATOR; Type 0: Not a Combination Product					

Marketing Information						
keting End Date						
2025						

Labeler - Aplicare Products, LLC (081054904)

Registrant - Medline Industries, LP (025460908)

Revised: 12/2022 Aplicare Products, LLC