

APLICARE POVIDONE IODINE SWABSTICK- 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 Povidone Iodine Gel Swabstick

Drug Facts

Active ingredient

Povidone-iodine USP 10%

Purpose

Antiseptic

Use

antiseptic skin preparation

Warnings

For external use only

Do not use

- if allergic to iodine
- in the eyes

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
- infection occurs

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

Avoid excessive heat. Store at room temperature.

Directions

apply locally as needed

Other information

- 1% titratable iodine
- not made with natural rubber latex
- for hospital or professional use only

Inactive ingredients

disodium phosphate, glycerin, hydroxy ethylcellulose, nonoxynol-10, simethicone, water

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

800-760-3236

Monday-Friday 8:30 a.m.- 5:00 p.m. EST

PRINCIPAL DISPLAY PANEL - 1 Swabstick Packet

NDC 52380-5972-1

APLICARE

□ Tear Here Hold Upright Tear Here □

ONE

POVIDONE-IODINE

GEL SWABSTICK

ANTISEPTIC

Non-Sterile Solution

One 4-inch saturated swabstick

Reorder No. S-1148

NDC 52380-5972-1



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APLICARE, INC.

MERIDEN, CT 06450

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www.aplicare.com

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(01)00352380597213



Drug Facts (continued)

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disodium monoxynol-10, simethicone, water phosphate, glycerin, hydroxy ethylcellulose,



LOT

APLICARE POVIDONE IODINE SWABSTICK

povidone iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52380-5972
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
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
HYDROXYETHYL CELLULOSE (2000 MPAS 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:52380-5972-1	2 mL in 1 PACKET; Type 0: Not a Combination Product	05/31/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/31/2017	

Labeler - Aplicare Products, LLC (081054904)

Establishment

Name	Address	ID/FEI	Business Operations
Aplicare Products, LLC		081054904	manufacture(52380-5972)