APLICARE POVIDONE-IODINE SCRUB SPONGE STICKS- povidone-iodine scrub solution Aplicare, Inc.

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 Scrub Sponge Sticks

Drug Facts

Active ingredient

Povidone-iodine USP 10%

Purpose

Antiseptic

Use

antiseptic skin preparation

Warnings

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

For external use only

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

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

Avoid excessive heat. Store at room temperature.

Directions

use sponges to prep desired area

Other information

- 1% titratable iodine
- for single use only

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

Inactive ingredients

ammonium nonoxynol-4 sulfate, citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, 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 - 2 Sponge Stick Packet

NDC 52380-4124-2

APLICARE

Tear Here Hold Upright Tear Here

TWO POVIDONE-IODINE SCRUB SPONGE STICKS

ANTISEPTIC
Non-Sterile Solution

Two 8-inch Sponge Sticks Saturated with Povidone-Iodine Scrub USP

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Drug Facts (continued)

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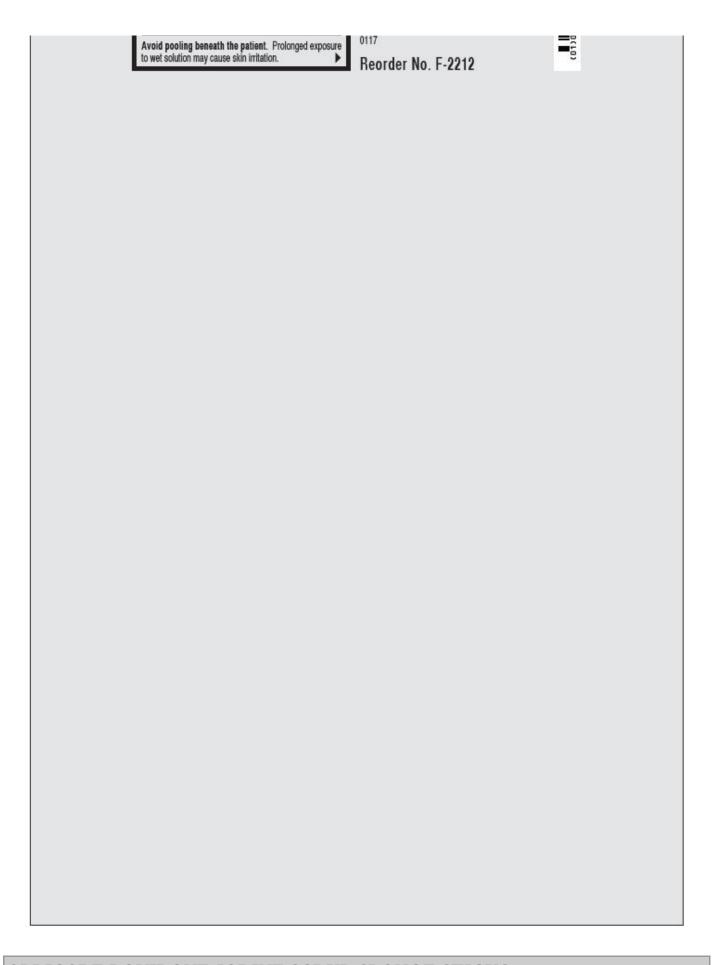
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APLICARE POVIDONE-IODINE SCRUB SPONGE STICKS

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52380-4124	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PO VIDO NE-IO DINE (UNII: 85H0 HZU99M) (IO DINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		
NONOXYNOL-9 (UNII: 48Q180SH9T)		
AMMO NIUM NO NO XYNO L-4 SULFATE (UNII: 9HIA70 O 4J0)		
WATER (UNII: 059QF0KO0R)		

Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:52380-412	24-2 90 mL in 1 PACKET; Type 0: Not a Combination Proc	duct 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, Inc. (107255002)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aplicare, Inc.		107255002	manufacture(52380-4124)	

Revised: 5/2017 Aplicare, Inc.