APLICARE POVIDONE-IODINE SCRUB LARGE WING SPONGE- 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 Large Wing Sponge

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 Packet

NDC 52380-0124-2

***A*PLICARE**

 Tear Here Hold Upright Tear Here

TWO POVIDONE-IODINE SCRUB
LARGE WINGED SPONGES

ANTISEPTIC
Non-Sterile Solution

Two Large Winged Sponges Saturated with
Povidone-Iodine Scrub USP

Reorder No. F-2012

NDC 52380-0124-2

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APLICARE, INC., MERIDEN, CT 06450 U.S.A.

www.aplicare.com

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0117

Reorder No. F-2012

APLICARE POVIDONE-IODINE SCRUB LARGE WING SPONGE

povidone-iodine scrub solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52380-0124
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, UNSPECIFIED FORM (UNII: GR686LBA74)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
AMMONIUM NONOXYNOL-4 SULFATE (UNII: 9HIA70O4J0)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52380-0124-2	120 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, Inc. (107255002)

Establishment			
Name	**Address**	**ID/FEI**	**Business Operations**
Aplicare, Inc.		107255002	manufacture(52380-0124)

Revised: 5/2017 Aplicare, Inc.