

APLICARE POVIDONE-IODINE SCRUB SMALL 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 Small 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 - 4 Sponge Packet

NDC 52380-5124-4

APLICARE

□ Tear Here Hold Upright Tear Here □

**FOUR POVIDONE-IODINE SCRUB
SMALL WINGED SPONGES****ANTISEPTIC****Non-Sterile Solution**

Four Small Winged Sponges Saturated with
Povidone-Iodine Scrub USP

Reorder No. F-4012

NDC 52380-5124-4



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

www.aplicare.com



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APLICARE POVIDONE-IODINE SCRUB SMALL WING SPONGE

povidone-iodine scrub solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52380-5124
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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-5124-4	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(52380-5124)

Revised: 5/2017

Aplicare, Inc.