

## **APLICARE POVIDONE-IODINE - povidone-iodine douche**

**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.*

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### **Drug Facts**

Povidone-Iodine USP 10% (0.16% when diluted)

Antiseptic

For temporary relief of minor itching and irritation

Do not use if sensitive to iodine

For vaginal use only

Stop use and ask a doctor if

- symptoms persist for more than 7 days you have pain or tenderness in the lower part of the abdomen and pelvis
- you have vaginal discharge or bleeding, chills, nausea, or fever
- your vaginal discharge is an unusual amount, color or odor
- you have frequent and painful urination
- douching results in pain, soreness, swelling, redness, itching, excessive dryness or irritation

If pregnant or breast-feeding, ask a health professional before use

Use twice weekly unless directed by a physician. Add 1/2 fluid ounce (one tablespoonful) to 1 quart of lukewarm water. For other uses consult a physician.

Questions or comments?

1 800 760-3236 (M-F 8:30 AM - 5:00 PM EST)

Povidone-iodine Douche

**APLICARE**  
 NDC 52380-1730-8 Reorder No. 82-236  
**POVIDONE-IODINE DOUCHE**

APLICARE, INC.  
 Meriden, CT 06450-7172  
 www.aplicare.com  
 Made in U.S.A.  
 L256-0107

8 Fl. Oz. (237mL)

**Drug Facts**  
**Active ingredient** Purpose  
 Povidone-iodine (USP 10% I) 10% when diluted. Antiseptic

**Use**  
 For temporary relief of minor itching and irritation. ▶

**Drug Facts, cont.**  
**Warnings**  
 ■ Do not use if sensitive to iodine  
 ■ For vaginal use only

**Stop use and ask a doctor if**  
 ■ symptoms persist for more than 7 days  
 ■ you have pain or tenderness in the lower part of the abdomen and pelvis ■ you have vaginal discharge or bleeding, chills, rashes, or fever  
 ■ your vaginal discharge is an unusual amount, color or odor ■ you have frequent and painful urination  
 ■ douching results in pain, soreness, swelling, redness, itching, excessive dryness or irritation

If pregnant or breast-feeding, ask a health professional before use.

**Keep out of reach of children.** If swallowed get medical help or contact a Poison Control Center immediately.

**Directions** Use twice weekly unless directed by a physician. Add 1/2 fluid ounce (one tablespoonful) to 1 quart of lukewarm water. For other uses consult a physician.

**Other information** ■ a douche is not a contraceptive and should not be used to prevent pregnancy ■ avoid excessive heat (104 °F / 40 °C) ■ non-staining to skin and natural fabrics

**Inactive ingredients** disodium phosphate, fragrance, glycerin, nonoxynol-10, simethicone, water

**Questions or comments?**  
 ■ 1 800 760-2836 (M - F 8:30 AM - 5:00 PM EST)

## APLICARE POVIDONE-IODINE

povidone-iodine douche

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52380-1730
<b>Route of Administration</b>	VAGINAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Povidone-iodine</b> (UNII: 85H0HZU99M) (Iodine - UNII:9679TC07X4)	Povidone-iodine	10 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Nonoxynol-10</b> (UNII: K7O76887AP)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Sodium Phosphate, Dibasic Anhydrous</b> (UNII: 22ADO53M6F)	
<b>Water</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-1730-2	60 g in 1 BOTTLE		
2	NDC:52380-1730-8	240 g in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	09/01/1998	

**Labeler** - Aplicare, Inc. (107255002)

## Establishment

Name	Address	ID/FEI	Business Operations
Aplicare, Inc.		058377631	manufacture

Revised: 4/2010

Aplicare, Inc.