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.

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

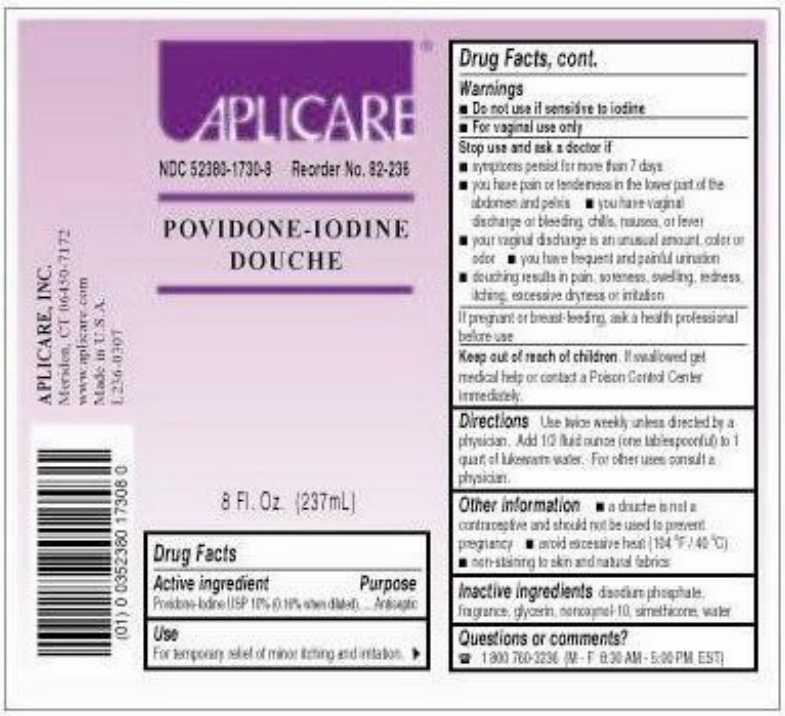
- symptoms persist for more than 7 days you have pain or tenderness in the lower part of the abdomen and pelvis
- you have vaginal discharge or bleeding, chills, nausea, or fever
- your vaginal discharge is an unusual amount, color or odor
- you have frequent and painful urination
- douching results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

povidone-iodine douche

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52380-1730
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Povidone-iodine (UNII: 85H0HZU99M) (Iodine - UNII:9679TC07X4)	Povidone-iodine	10 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
Nonoxynol-10 (UNII: K7O76887AP)	
Glycerin (UNII: PDC6A3C0OX)	
Dimethicone (UNII: 92RU3N3Y1O)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Sodium Phosphate, Dibasic Anhydrous (UNII: 22ADO53M6F)	
Water (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.