

APLICARE POVIDONE-IODINE PERINEAL WASH - povidone-iodine perineal wash liquid 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

Antiseptic

Stop use and ask a doctor if

- infection occurs
- redness, irritation, swelling or pain persists or increases

Ask a doctor before use if injuries are

- deep puncture wounds
- serious burns

Do not use if allergic to iodine.

Do not use in eyes.

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

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

Bottle Label

APLICARE
NDC 52080-1080-8 Reorder No. 02-230
POVIDONE-IODINE
PERINEAL WASH
CONCENTRATE
8 Fl. Oz. (237mL)

APPLICARE, INC.
Meriden, CT 06450-7172
www.aplicare.com
Made in U.S.A.
L230-0708

(01) 0 0302380 18808 4

Drug Facts	
Active ingredient	Purpose
Povidone-Iodine USP 10%	Antiseptic
Use: cleansing and deodorizing	
Warnings	
Do not use if allergic to iodine	
Ask a doctor before use if injuries are	
■ deep puncture wounds ■ serious burns	

Drug Facts, cont.
Warnings Cont.
Stop use and ask a doctor if
■ infection occurs ■ redness, irritation, swelling or pain persists or increases
Do not use in eyes
Avoid "pooling" beneath patient. Prolonged exposure to wet solution may cause skin irritation.
Keep out of reach of children. In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.

Directions ■ Fill the dispenser bottle to the bottom line (10 cc) with Aplicare[®] Perineal Wash Concentrate ■ Add approximately 7 1/2 oz of lukewarm or cool water to the top line (5 cc) ■ Pull cap nozzle up to OPEN. ■ Squeeze the dispenser gently, directing the flow to the perineal area while seated on the toilet or in the tub or standing in the shower. Irrigate the entire area, front and back until the dispenser bottle is empty. May be allowed to dry on the skin, or washed off, as desired.

Other information ■ avoid excessive heat (104°F (40°C) ■ non-staining to skin and natural fabrics

Inactive ingredients disodium phosphate, fragrance, glycerin, nonoxonyl-10, simethicone, xanthan

Questions or comments?
☎ 1 800 760 3296 (M - F 9:30 AM - 5:00 PM EST)

APLICARE POVIDONE-IODINE PERINEAL WASH povidone-iodine perineal wash liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52380-1880	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
Povidone-iodine (UNII: 85H0HZU99M) (Iodine - UNII:9679TC07X4)		Povidone-iodine	10 in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
Nonoxynol-10 (UNII: K7O76887AP)				
Glycerin (UNII: PDC6A3C0OX)				
Silicon Dioxide (UNII: ETJ7Z6XBU4)				
Dimethicone (UNII: 92RU3N3Y1O)				
Sodium Phosphate, Dibasic Anhydrous (UNII: 22ADO53M6F)				
Water (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-1880-8	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: 3/2010

Aplicare, Inc.