FIRST AID ONLY POVIDONE-IODINE ANTISEPTIC- povidone-iodine swab
Acme United Corporation

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.

First Aid Only Povidone-Iodine Antiseptic Pads

Active Ingredient:

Povidone-Iodine Solution 10%

Purpose:

Antiseptic

Use:

First aid antiseptic to help prevent skin infection.

Warnings:

For external use only.

Do not use▪ in eyes ▪ over large areas of the body ▪ if allergic to any of the ingredients

▪ longer than 1 week unless directed by a doctor.

Ask doctor before use if you have ▪ deep or puncture wounds ▪ animal bites ▪ serious burns.

Stop use and ask a doctor if ▪ conditions worsen or clear up and then recur

▪ the condition persists for more than 7 days

Keep out of the reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions:

Open packet and wipe affected area. Apply 1 to 3 times daily. May be covered with a sterile bandage. If bandaged, let dry first..

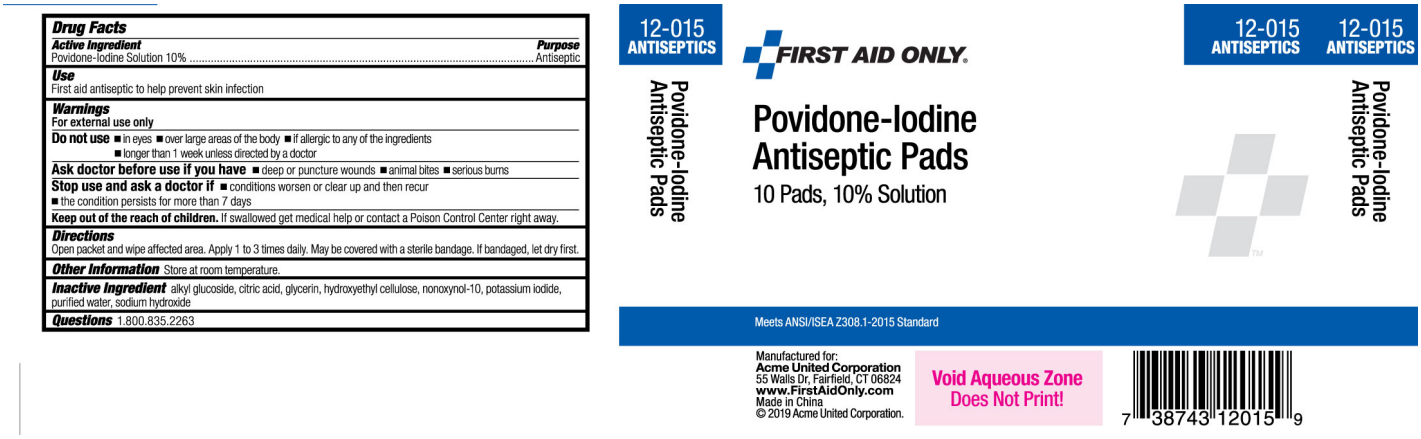
Other Information:

Store at room temperature..

Inactive Ingredients:

alkyl glucoside, citric acid, glycerin, hydroxyethyl cellulose, nonoxynol-10, potassium iodide,

purified water, sodium hydroxide



FIRST AID ONLY POVIDONE-IODINE ANTISEPTIC

povidone-iodine swab

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0924-8112(NDC:65517-0034)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (UNII: S38J6RZN16)	
NONOXYNOL-10 (UNII: K7O76887AP)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM IODIDE (UNII: 1C4QK22F9J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-8112-01	10 in 1 CARTON	01/07/2020	
1		0.5 mL in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0924-8112-00	0.5 mL in 1 POUCH; Type 0: Not a Combination Product	01/07/2020	
3	NDC:0924-8112-02	50 in 1 CARTON	01/07/2020	
3		0.5 mL in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:0924-8112-03	100 in 1 CARTON	01/07/2020	
4		0.5 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	01/07/2020	

Labeler - Acme United Corporation (001180207)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-8112) , repack(0924-8112)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-8112) , repack(0924-8112)

Revised: 1/2020 Acme United Corporation