FIRST AID ONLY POVIDONE-IODINE ANTISEPTIC- povidone-iodine patch
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 Pad

Drug Facts

Active ingredient

Povidone-Iodine 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

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Ask a 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 reach of children.

If swallowed get medical help or contact a Poison Control Center right away.

Driections

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.

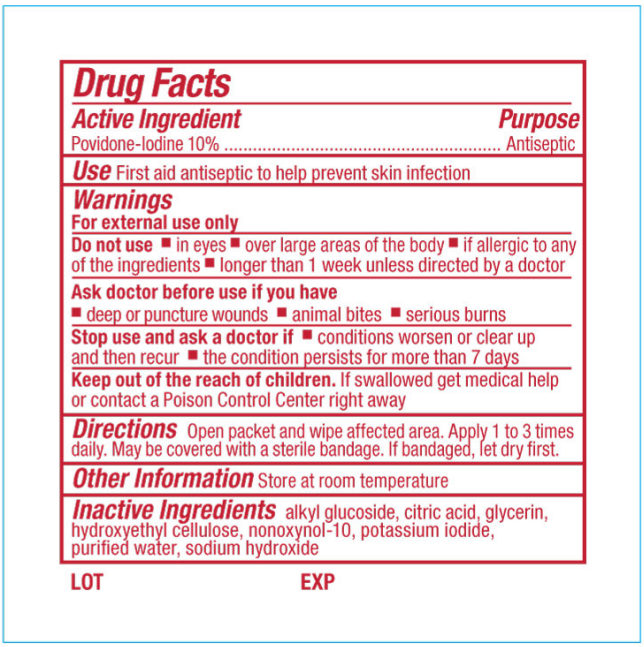
Inactive ingredients:

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

purified water, sodium hydroxide

Pouch label

Front



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FIRST AID ONLY POVIDONE-IODINE ANTISEPTIC

povidone-iodine patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0924-8113(NDC:59050-455)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
NONOXYNOL-10 (UNII: K7O76887AP)	
POTASSIUM IODIDE (UNII: 1C4QK22F9J)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-8113-00	5.5 g in 1 POUCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	06/03/2022	
2	NDC:0924-8113-01	10 in 1 CARTON	06/03/2022	
2		5.5 g in 1 POUCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:0924-8113-02	50 in 1 CARTON	06/03/2022	
3		5.5 g in 1 POUCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/03/2022	

Labeler - Acme United Corporation (001180207)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-8113) , repack(0924-8113)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-8113) , repack(0924-8113)

Revised: 5/2022 Acme United Corporation