FIRST AID ONLY POVIDONE-IODINE PREP PAD- 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 Prep Pad

Active Ingredients

Active Ingredients Povidone Iodine 10%

Purpose

Purpose Antiseptic

Use

Use Antispetic for preparation of the skin.

Warnings

Warnings •For external use only.

•Discontinue use if irritation and redness develop.

•Keep out of reach of children.

Keep out of reach of children

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

Directions

Directions Apply locally as needed.

Other Information

Other Information Store at room temperature 15° - 30°C (59° - 86°F)

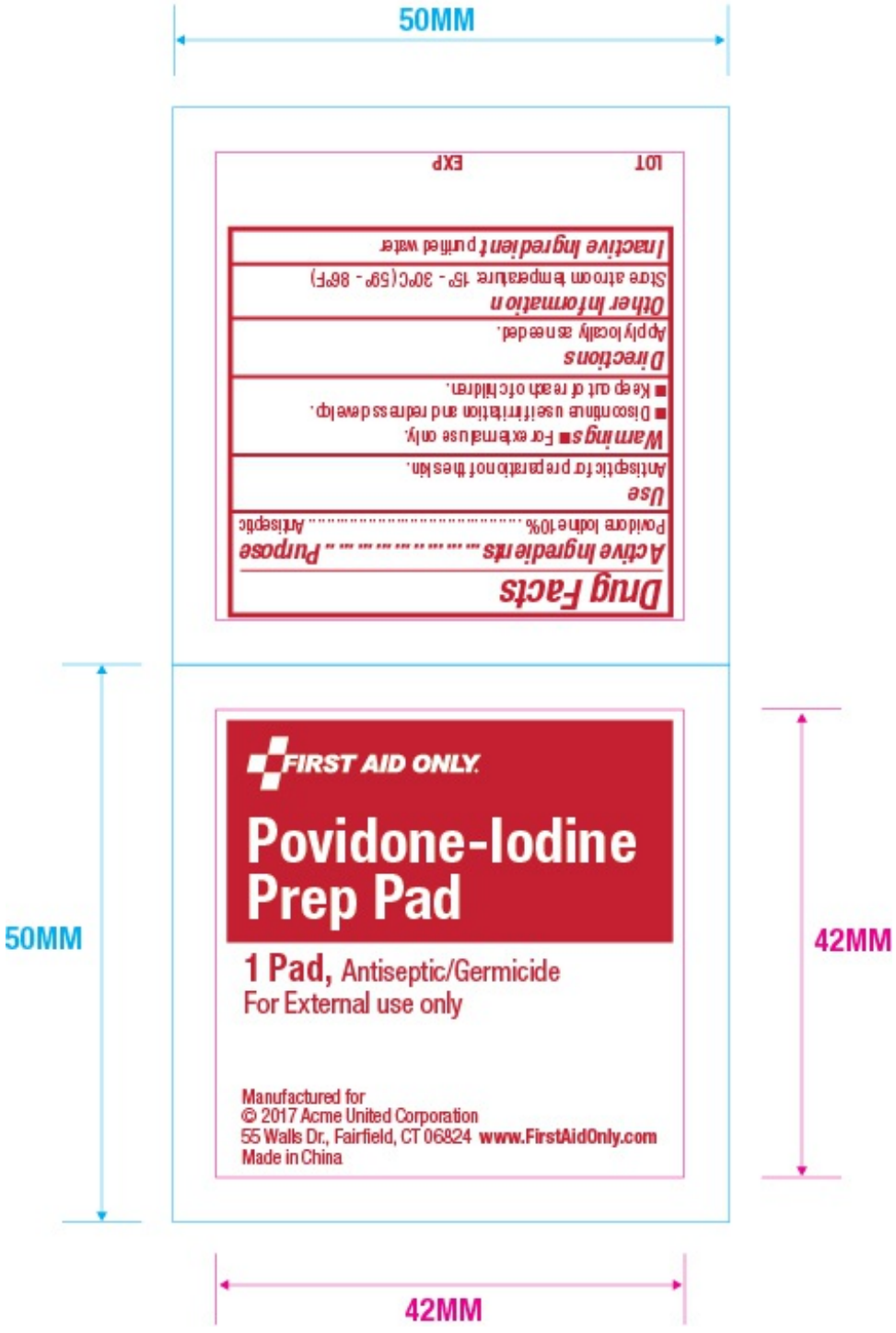
Inactive Ingredient

Inactive Ingredient purified water

Package Principal Display Panel

Component#	M337
Description	Povidone-Iodine Prep Pad, Wrapper Art (Planet)
Version	revA
Date	05.31.17
Specs	See Dieline / 1C (Pantone 200)

Drug Facts by Planet



FIRST AID ONLY POVIDONE-IODINE PREP PAD

povidone-iodine patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0924-8110(NDC:44019-811)
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**
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-8110-00	1 in 1 POUCH	07/26/2017	
1		0.45 g in 1 PATCH; 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	part333A	07/24/2017	

Labeler - Acme United Corporation (001180207)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-8110) , repack(0924-8110)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-8110) , repack(0924-8110)

Revised: 7/2017 Acme United Corporation