

## **PVP IODINE- povidone-iodine swab**

### **HART Health**

*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.*

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## **PVP IODINE WIPES**

### **Active Ingredient**

Povidone Iodine 10% (equivalent to 1% titratable iodine)

### **Purpose**

Topical Antiseptic

### **Uses**

First aid topical antiseptic to help prevent infection in:

- minor cuts
- scrapes
- burns
- abrasions

### **Warnings**

For external use only

### **Do not use**

- in the eyes or over large portions of the body
- on serious burns
- on animal bites
- on deep or puncture wounds

### **Stop use and ask a doctor if**

- symptoms last more than 72 hours
- redness, swelling, irritation or pain occurs

### **Keep out of reach of children**

If swallowed get medical help or contact a Poison Control Center right away 1-800-222-1222

## Directions

Adults and children 12 years of age and over:

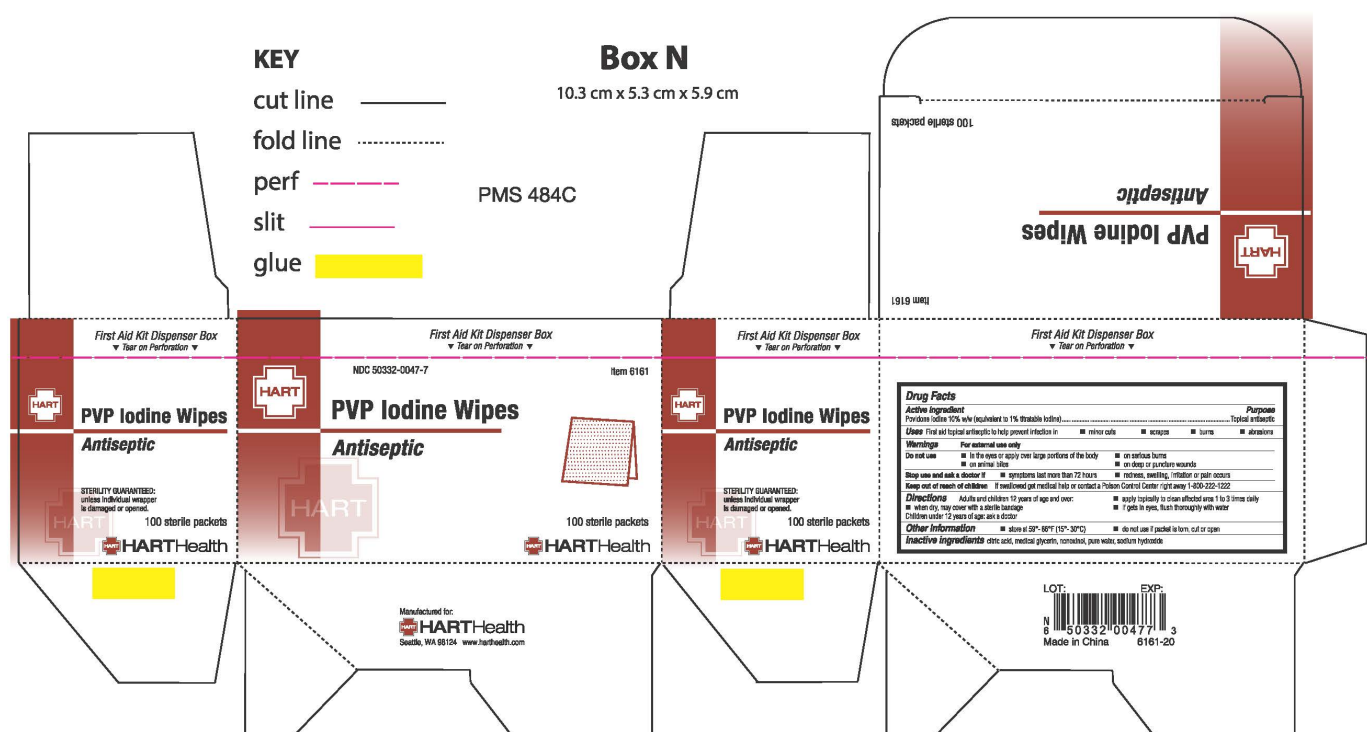
- apply topically to clean affected area 1 to 3 times daily
- when dry, may be covered with a sterile bandage
- if gets in eyes, flush thoroughly with water

Children under 12 years of age:

- ask a doctor

## Inactive Ingredients

Citric Acid, Glycerin, Nonoxynol, Sodium Hydroxide, Water



# KEY

cut line ————

fold line .....

perf - - - - -

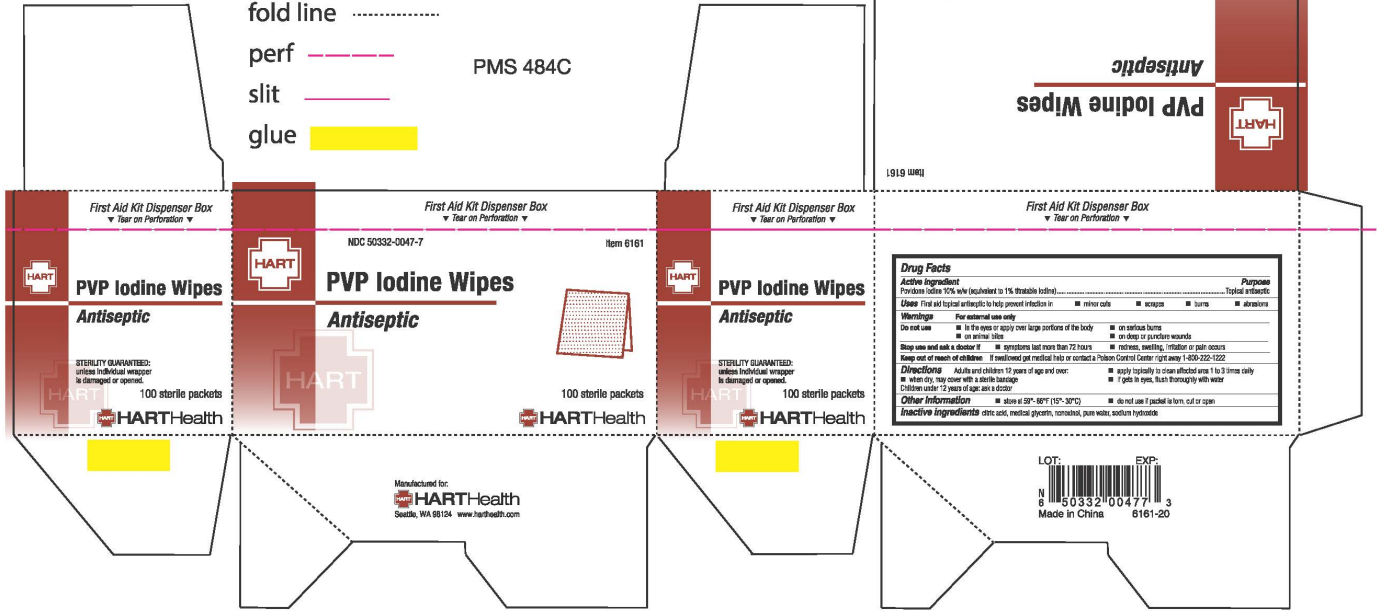
slit ————

glue

# Box N

10.3 cm x 5.3 cm x 5.9 cm

PMS 484C



# KEY

cut line ————

fold line .....

perf - - - - -

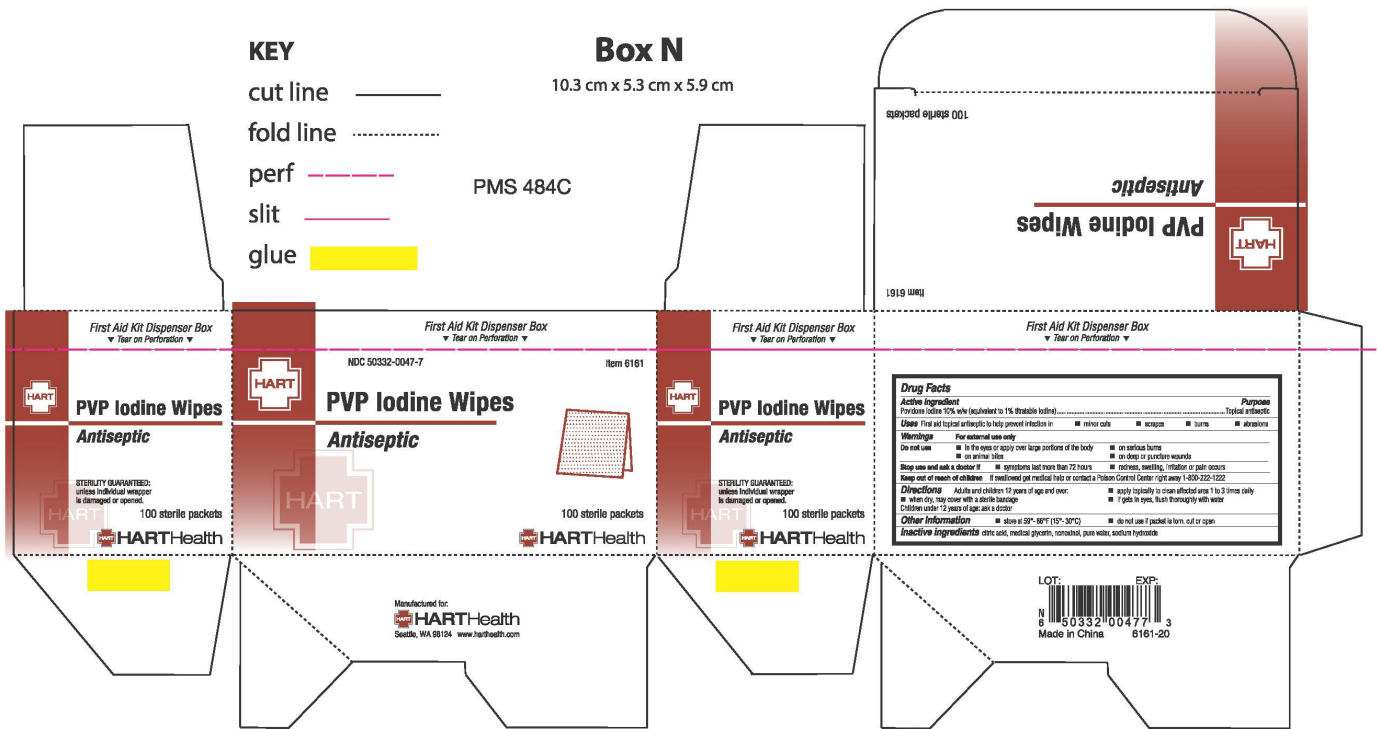
slit ————

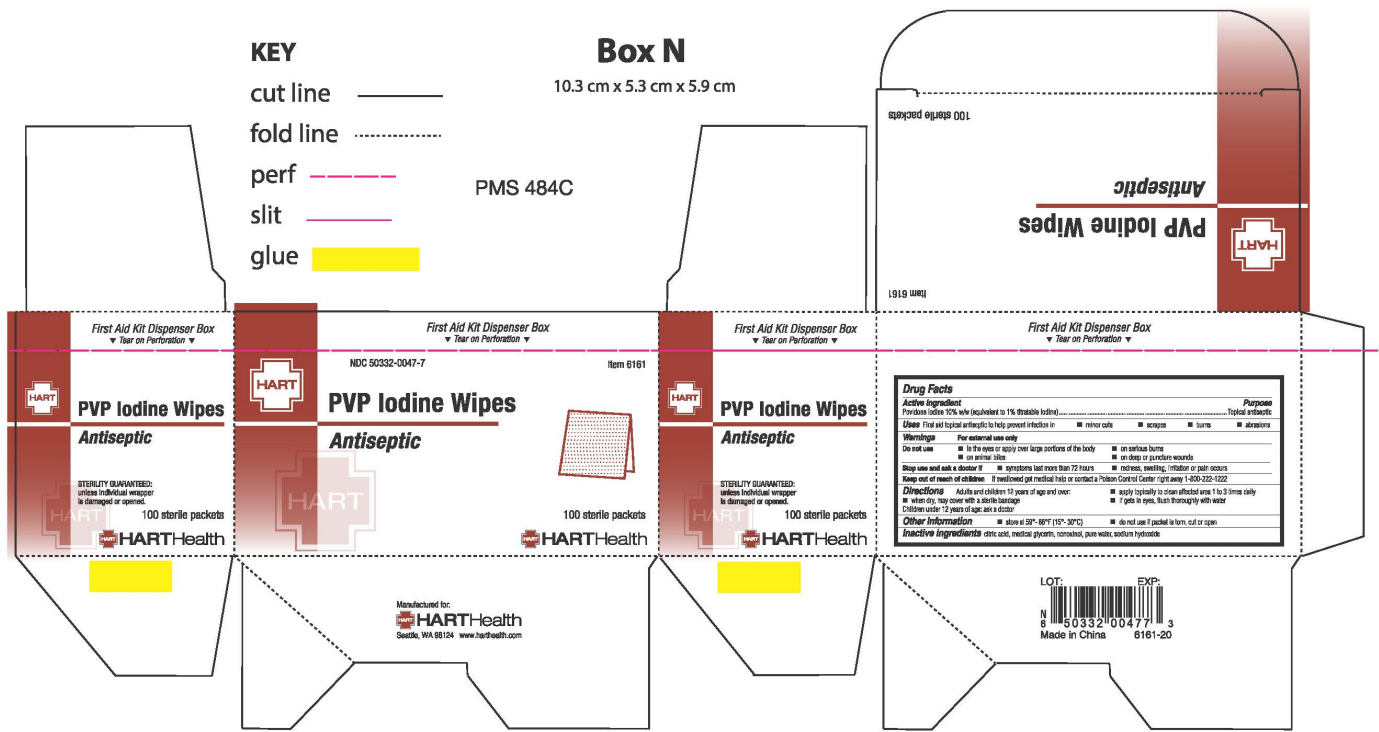
glue

# Box N

10.3 cm x 5.3 cm x 5.9 cm

PMS 484C





## PVP IODINE

povidone-iodine swab

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50332-0047
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 1 g

### Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-	10 in 1 BOX	04/01/1974	

1	0047-0	10 in 1 BOX	04/01/1974	
1		.35 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50332-0047-7	100 in 1 BOX	04/20/2016	
2		.35 g in 1 PACKET; 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	part333A	04/01/1974	

**Labeler** - HART Health (069560969)

**Registrant** - HART Health (069560969)

### Establishment

Name	Address	ID/FEI	Business Operations
Jiangsu Province JianErKang Medical		530968767	manufacture(50332-0047)