

**NON-STERILE- povidone-iodine patch**  
**Changzhou Maokang Medical Products Co., Ltd**

*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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**Povidone-Iodine Solution, Non-sterile**

***Drug Facts***

***Active ingredient***

Povidone-Iodine 10%w/w

***Purpose***

Antiseptic

***Use***

for antiseptic skin preparation

***Warnings***

**do not use**

- if allergic to Iodine
- do not use in the eye

**Stop use and ask a doctor if**

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

**Keep out of reach of children.**

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

***Avoid pooling beneath patient.***

**Ask a doctor before use if injuries are**

- deep or puncture wounds
- serious burns

***Directions***

apply locally as needed

***Other information***

- 1% titratable iodine
- for hospital or professional use only

***Inactive ingredients:***

Citric Acid, Alkyl Glucoside, Hydroxyethyl, Cellulose, Nonoxynol-10, Glycerin, Sodium Hydroxide, Potassium Iodide, Purified Water.

Package Labeling:

**Tear Here**  
**Pour**

**NDC59050-552-10**

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LOT



**Rev.A**

**For external use only.**

**NOT MADE WITH  
natural rubber latex**

Single Use Only



**Non Sterile**

Manufactured by  
Changzhou Maokang Medical Products Co., Ltd  
Add: No.9-P, The North of Danyang Road, Jintan City,  
Changzhou, Jiangsu Province, China. P.C.: 213200  
Tel: +86-519-80186516; Fax: +86-519-80186502  
Made in China

CAUTION:

Antiseptic Non Sterile Solution

Reorder:110702002

0.75 Fl.oz. (22.5ml)

3/4 FLUID OUNCE

Povidone-Iodine  
Solution

Maokang Medical



Tear Here  
Pour

## NON-STERILE

povidone-iodine patch

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59050-553
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
NONOXYNOL-10 (UNII: K7O76887AP)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
POTASSIUM IODIDE (UNII: 1C4QK22F9J)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59050-553-11	22.5 g in 1 POUCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	06/29/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/29/2018	

**Labeler** - Changzhou Maokang Medical Products Co., Ltd (421317073)

### Establishment

Name	Address	ID/FEI	Business Operations
Changzhou Maokang Medical Products Co., Ltd		421317073	manufacture(59050-553)

Revised: 9/2018

Changzhou Maokang Medical Products Co., Ltd