

**POVIDONE IODINE PREP- povidone-iodine solution**  
**Jianerkang Medical Co., Ltd**

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**Povidone Iodine Prep Swabstick**

***Drug Facts***

***Active ingredient***

Povidone Iodine USP, 7.5% W/V (equivalent to 0.75% titratable iodine)

***Purpose***

Antiseptic

***Use***

- Health-care antiseptic for preparation of the skin prior to surgery
- First aid antiseptic to help prevent the risk of skin infection in minor cuts, scrapes, and burns.

***Warnings***

**For external use only.**

**Do not**

- use in the eyes
- use on individuals who are allergic or sensitive to iodine
- apply over large areas of the body
- use as a first aid antiseptic longer than 1 week unless directed by a doctor. Discontinue use if irritation and redness develop. Consult a doctor in case of
- deep or puncture wounds
- animal bites
- serious burns.

**Stop use and consult a doctor**

if the condition persists or gets worse.

**Keep out of reach of children.**

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

***Directions***

**For preparation of the skin prior to surgery**

- clean the affected area remove swab by stick

- apply to the operative site prior to surgery. For use as a first aid antiseptic
- clean the affected area
- apply a small amount of this product on the area 1-3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first.

### Other information

store at room temperature: 15°–30°C(59°-86°F)

- Avoid excessive heat

### Inactive ingredients

citric acid, purified water, sodium hydroxide, Nonoxynol-10, glycerin

### Package Labeling:

490c

## POVIDONE IODINE PREP

povidone-iodine solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:34645-5501
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZ U99M) (IODINE - UNII:9679TC07X4)	IODINE	7.5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

**NONOXYNOL-10** (UNII: K7O76887AP)

**GLYCERIN** (UNII: PDC6A3C0OX)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:34645-5501-0	10 in 1 CARTON	02/03/2017	
1		25 in 1 BOX		
1		0.045 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 Drug	M003	01/30/2017	

**Labeler** - Jianerkang Medical Co., Ltd (530968767)

### Establishment

Name	Address	ID/FEI	Business Operations
Jianerkang Medical Co., Ltd		530968767	manufacture(34645-5501)

Revised: 10/2023

Jianerkang Medical Co., Ltd