

## **POVIDINE IODINE - povidone iodine solution**

**Chain Drug Consortium, LLC**

*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 Prep**

#### **Active Ingredient**

Povidone Iodine 10% v/v

#### **Purpose**

Antiseptic

### **Uses: povidone iodine prep**

povidone iodine prep

- First aid antiseptic to help prevent skin infection in minor cuts, scrapes and burns.
- For preparation of the skin prior to surgery.
- Helps reduce bacteria that can potentially cause skin infections.

### **Warnings:**

- **FOR EXTERNAL USE ONLY**

### **Do not use:**

- As a first aid antiseptic for more than 1 week.
- In the eyes.
- Over large areas of the body.

### **Ask a doctor before use if you have:**

- Deep puncture wounds
- Animal bites
- Serious burns

### **Stop Use:**

- If irritation and redness develop
- If condition persists for more than 72 hours, consult a physician.

### **Keep Out Of Reach Of Children**

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

### **Directions:**

Tear at notch, remove applicator, use only once.

### As a first aid antiseptic

- clean affected area
- apply 1 to 3 times daily
- may be covered with a sterile bandage, if bandaged let dry.

### For preoperative patient skin preparation

- clean area
- apply to operative site prior to surgery using the applicator

### Inactive Ingredient:

Inactive Ingredient: Citric Acid, Glycerin, Sodium Citrate, Tween 80, Disodium Phosphate, Water

For use as an

- first aid antiseptic
- pre-operative skin preparation

### Principal Display Panel

povidone\_iodine\_prep

148 mm

83 mm

**A primary professional and hospital antiseptic used to help prevent infection.**


**DIRECTIONS:** For minor wounds, burns, and infections, apply directly to affected area. May be covered with gauze or adhesive bandage.

**ACTIVE INGREDIENTS:** Povidone-Iodine 10%

**INACTIVE INGREDIENTS:** Citric Acid, Glycerin, Sodium Citrate, Tween 80, Disodium Phosphate and Purified Water.

**CAUTION:** In case of deep puncture wounds, or serious burns, consult a physician. If redness, irritation, swelling, or pain persists or increases, or if infection occurs, discontinue use and consult a physician.


**WARNING:** For external use only. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Store at controlled room temperature 15°-30°C (59°-86°F). Equal to 1% available iodine.

 NDC# 68016-013-94


**Povidone Iodine  
Prep Solution  
U.S.P.**


Topical Antiseptic Microbicide

**NET WT. 8 fl. oz. (237ml)**

 If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

DISTRIBUTED BY:  
CHAIN DRUG CONSORTIUM  
3301 NW BOCA RATON BLVD  
SUITE 101, BOCA RATON, FL 33431  
MADE IN MEXICO

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## POVIDINE IODINE

povidine iodine solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-013
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
POVIDONE-IODINE (UNII: 85H0HZU99M) (POVIDONE-IODINE - UNII:85H0HZU99M)	POVIDONE-IODINE	10 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:68016-013-94	6 in 1 CASE		
1		236 mL in 1 BOTTLE		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part333C	03/17/2011	

**Labeler** - Chain Drug Consortium, LLC (101668460)

Revised: 5/2011

Chain Drug Consortium, LLC