

## **POVIDONE IODINE PREP- povidone iodine solution**

### **Cardinal 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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### **Drug Facts**

#### **Active ingredient**

Povidone Iodine 10%

(equivalent to 1% titratable iodine)

#### **Purpose**

Antiseptic/First Aid Antiseptic

#### **Uses**

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

#### **Warnings**

**For External Use Only.**

#### **Do not use**

As a first aid antiseptic

- Do not use in the eyes or apply over large areas of the body
- In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor
- Stop use and consult a doctor if the condition persists or gets worse
- Do not use longer than 1 week unless directed by a doctor

For preoperative patient skin preparation

- Do not use in the eyes
- Discontinue use if irritation and redness develop

- If condition persists for more than 72 hours, consult a doctor

**Keep out of reach of children.**

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

**Directions:**

Clean the affected area.

**For preparation of skin prior to surgery**

- Apply product to the operative site prior to surgery

**For first aid antiseptic**

- 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**

- Protect from freezing
- Avoid excessive heat

**Inactive Ingredients:**

Citric Acid, Disodium Phosphate, Nonoxynol-9, Sodium Hydroxide, Water

**Principal Display Panel**

Povidone-Iodine Prep Solution

Povidone-Iodine 10%

single use only

Cardinal Health

Net Wt. 0.75 fl oz (22.2 mL)

NDC 63517-132-01



<b>POVIDONE IODINE PREP</b>			
povidone iodine solution			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63517-132
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	1 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>NONOXYNOL-9</b> (UNII: 48Q180SH9T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63517-132-01	500 in 1 CASE	08/25/2016	
1		22.2 mL in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	08/26/2015	

**Labeler** - Cardinal Health (961027315)

Revised: 12/2022

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