

**POVIDINE IODINE- povidine iodine swab**  
**Dynarex Corporation**

*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 Swabstick**

Section Text

**Active Ingredient**

Povidone Iodine 10% v/v

**Purpose**

Antiseptic

**Purpose:**

Purpose:

- 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:**

Section Text

- **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 Povidone iodine:

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

### Other information:

Store at room temperature.

Avoid excessive heat

For use as an

- first aid antiseptic
- pre-operative skin preparation

### Inactive Ingredients

Inactive ingredients: nonoxynol-9, water

### Principal Display Panel

Principal Display Panel

Povidone Iodine Swabsticks 1201 & 1202

Povidone iodine.jpg

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**POVIDINE IODINE**

povidine iodine swab

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67777-130
<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) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:67777-130-01	50 in 1 BOX		
1		0.3 mL in 1 PACKET		
2	NDC:67777-130-02	25 in 1 BOX		
2		0.9 mL in 1 PACKET		

### 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	05/10/2010	

**Labeler** - Dynarex Corporation (008124539)

**Registrant** - Dynarex Corporation (008124539)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Sion Biotext Medical Ltd		532775194	manufacture(67777-130)

Revised: 12/2013

Dynarex Corporation