

**PVP-I PREP PADS FOIL-FOIL- povidone-iodine swab**  
**Dukal 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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**Drug Facts**

**Active Ingredient:**

Povidone Iodine USP 10%

**Purpose:**

Antiseptic

**Use:**

For preparation prior to surgery. Helps to reduce bacteria that can potentially cause skin infection.

**Warnings:**

**For external use only.**

Do not apply to persons allergic to iodine. Do not use in the eyes.

- Ask a doctor before use if injuries are deep wounds, puncture wounds, serious burns.
- Stop use and ask a doctor if irritation and redness develop, condition persists for more than 72 hours, infection occurs.
- Avoid pooling beneath the patient. Prolonged exposure to wet solution may cause skin irritation.
- **Keep out of reach of children**
- If swallowed or gets in eyes, get medical help or contact a Poison Control Center right away.

**Directions:**

Clean the area. Apply product to the operative site prior to surgery using pad to prep desired area.

**Other Information:**

1% titratable iodine, for hospital or professional use only. Store at ambient temperatures.

**Inactive Ingredients:**

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

**Principal Display Panel - PVP-I Prep Pads Foil Pouch Label**

**DUKAL™**  
**CORPORATION**

**REF 882**

**STERILE**

**Povidone-Iodine  
Prep Pad**

**For Professional and Hospital Use**

**Not Made with Natural Rubber Latex**

**1  
/Pouch**

**Manufactured For:**

**DUKAL CORPORATION • (631) 656-3800**

Ronkonkoma, NY 11779 • www.dukal.com

Made in China

**2**

<b>Drug Facts</b>	
<b>Active Ingredient</b> Povidone Iodine USP 10%.....	<b>Purpose</b> .....Antiseptic
<b>Use</b> For preparation of the skin prior to surgery	
<b>Warnings</b> <b>For external use only.</b>	
Do not apply to persons allergic to iodine. <b>Do not use</b> in the eyes. ■ Ask a doctor before use if injuries are deep wounds, puncture wounds, serious burns. ■ <b>Keep out of reach of children</b> ■ If swallowed or gets in eyes, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> Clean area. Apply to the operative site prior to surgery	
<b>Other Information</b> 1% titratable iodine. Store at ambient temperatures.	
<b>Inactive Ingredients</b> alkyl glucoside, citric acid, glycerin, hydroxyethyl cellulose, nonoxynol-10, potassium iodide, purified water, sodium hydroxide	

**Principal Display Panel - PVP-I Prep Pads Foil 865-8000 Case Label**

**DUKAL™  
CORPORATION**

**REF 882-8000**

**STERILE**

**POVIDONE-IODINE  
PREP PADS**

**For Professional and Hospital Use**

**Not Made with Natural Rubber Latex**

**8000/Case**

1/Pack

2

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Ronkonkoma, NY 11779 • www.dukal.com

Made in China, Hecho en China, Fabriqué en Chine

(01) 40665973025023



## PVP-I PREP PADS FOIL-FOIL

povidone-iodine swab

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65517-0034
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	1 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (2000 MPAS AT 1%) (UNII: S38J6RZN16)	
NONOXYNOL-10 (UNII: K7O76887AP)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	
POTASSIUM IODIDE (UNII: 1C4QK22F9J)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65517-0034-1	8000 in 1 CASE	01/31/2018	
1		0.5 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 not final	part333E	01/31/2018	

**Labeler** - Dukal Corporation (791014871)

Revised: 12/2019

Dukal Corporation