

PVP-I PREP PADS PAPER-FOIL- povidone-iodine swab
Dukal LLC

65517-0039-1

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 Paper/Foil Pouch Label

Dukal

Povidone-Iodine

Prep Pad

Non-Sterile

Antiseptic

For Professional and Hospital Use

Not Made with Natural Rubber Latex

Manufactured For: Dukal LLC


1(800)243-0741 / Ronkonkoma, NY 11779

Made in China

Dukal is a trademark registered in the

US Patent & Trademark Office by Dukal, LLC

1 Per Pouch / 2 / NDC 65517-0039-1 / REF 914

 <p>Povidone-Iodine Prep Pad</p> <p>Non-Sterile</p> <p>Antiseptic For Professional and Hospital Use</p> <p>Not made with natural rubber latex</p> <p>Manufactured For: Dukal, LLC 1(800)243-0741 Ronkonkoma, NY 11779 Made in China Dukal is a trademark registered in the US Patent & Trademark Office by Dukal, LLC</p> <p style="text-align: right;">Rev0</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 20%;">1 Per Pouch</td> <td style="width: 20%; text-align: center;">⊗</td> <td style="width: 40%;">NDC 65517-0039-1</td> <td style="width: 20%; text-align: center;">REF 914</td> </tr> </table>	1 Per Pouch	⊗	NDC 65517-0039-1	REF 914	<p>Drug Facts</p> <table border="1" style="width: 100%;"> <thead> <tr> <th style="width: 70%;">Active Ingredient</th> <th style="width: 30%;">Purpose</th> </tr> </thead> <tbody> <tr> <td>Povidone Iodine USP 10%.....</td> <td>Antiseptic</td> </tr> </tbody> </table> <p>Use For preparation of the skin prior to surgery</p> <p>Warnings For external use only.</p> <p>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. ■ Keep out of reach of children ■ If swallowed or gets in eyes, get medical help or contact a Poison Control Center right away.</p> <p>Directions Clean area. Apply to the operative site prior to surgery</p> <p>Other Information 1% titratable iodine. Store at ambient temperatures.</p> <p>Inactive Ingredients alkyl glucoside, citric acid, glycerin, hydroxyethyl cellulose, nonoxynol-10, potassium iodide, purified water, sodium hydroxide</p>	Active Ingredient	Purpose	Povidone Iodine USP 10%.....	Antiseptic
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povidone-iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65517-0039
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 MPA.S AT 1%) (UNII: S38J6RZN16)	
NONOXYNOL-10 (UNII: K7O76887AP)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	
POTASSIUM IODIDE (UNII: 1C4QK22F9J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65517-0039-1	1 in 1 POUCH	02/15/2023	
1		0.5 mL in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003	02/15/2023	

Labeler - Dukal LLC (791014871)