

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

65517-0034

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****Povidone-Iodine Prep Pad****Sterile****Antiseptic****For Professional and Hospital Use**

Not made with natural rubber latex

Sterile unless package is damaged or opened.

Manufactured For: Dukal, LLC

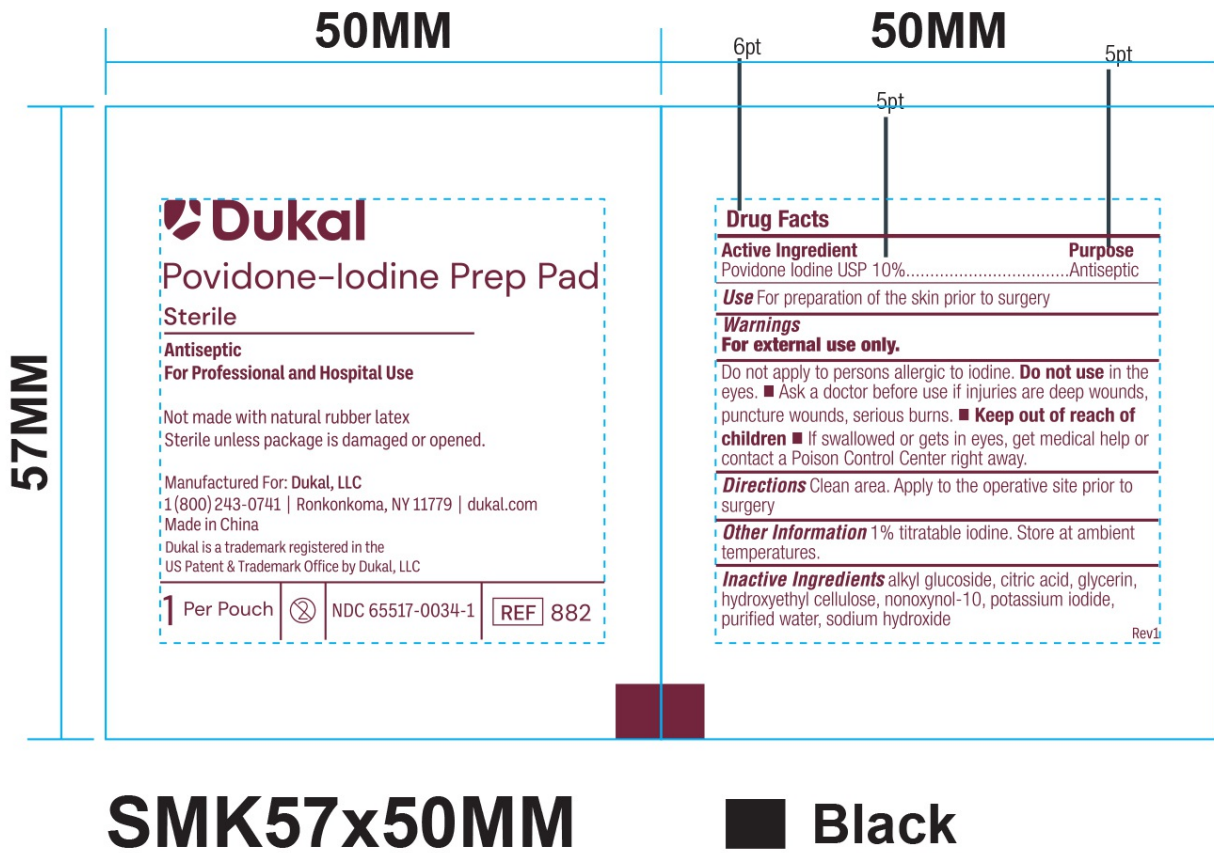
1(800)243-0741 / Ronkonkoma, NY 11779 / dukal.com

Made in China

Dukal is a trademark registered in the

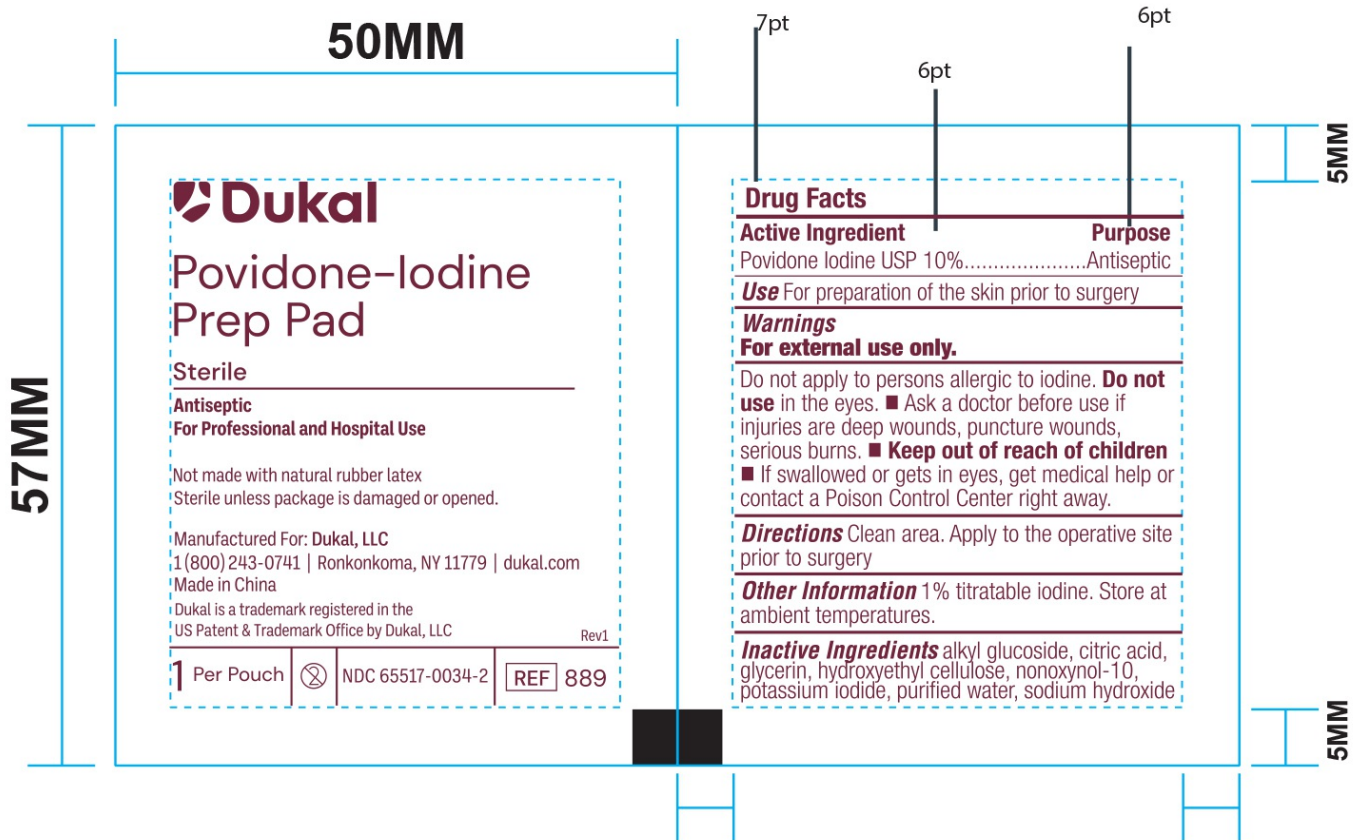
US Patent & Trademark Office by Dukal, LLC

1 Per Pouch - 2 - NDC 6551-0034-1 - REF 882



Principal Display Panel - PVP-I Prep Pads Paper Pouch Label

Dukal
Povidone-Iodine Prep Pad
Sterile
Antiseptic
For Professional and Hospital Use
Not made with natura rubber latex
Sterile unless package is damaged or opened.
Manufactured For: Dukal, LLC
1(800)243-0741 / Ronkonkoma, NY 11779 / dukal.com
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US Patent & Trademark Office by Dukal, LLC Rev1
1 Per Pouch - 2 - NDC 6551-0034-2 - REF 889



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: 85H0HZ U99M) (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:65517-0034-1	8000 in 1 CASE	01/31/2018	
1		0.5 mL in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:65517-0034-2	4000 in 1 CASE	01/31/2018	
2		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 Drug	M003	01/31/2018	

Labeler - DukaI LLC (791014871)

Revised: 2/2024

DukaI LLC