PVP-I POUCH FOIL-FOIL- povidone-iodine solution
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.

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.

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 3/4 Ounce Solution Sterile 885-500 Pouch Label

DUKAL™
CORPORATION

REF 885

STERILE

POVIDONE-IODINE
SOLUTION
3/4 OUNCE

For Professional and Hospital Use

Not Made with Natural Rubber Latex

1
/Pouch

DUKAL CORPORATION • (631) 656-3800

Ronkonkoma, NY 11779 • www.dukal.com

Made in China, Hecho en China, Fabriqué en Chine

2

D02231803

DUKAL™ CORPORATION

REF 885

NDC 65517-0035-1

POVIDONE-IODINE 3/4 OZ. SOLUTION

ANTISEPTIC **STERILE**

Drug Facts

Active ingredient	Purpose
Povidone Iodine USP 10%	Antiseptic

Use Patient preoperative skin preparation: Helps to

with natural rubber latex

Inactive ingredients alkyl glucoside, citric acid, glycerin, hydroxyethyl cellulose, nonoxynol-10, potassium iodide, purified water, sodium hydroxide

Questions? 1-800-243-0741

Manufactured For:
DUKAL CORPORATION
Ronkonkoma, NY 11779 ■ www.dukal.com

Made in China
¾ oz.
D022318O3
(01)10665973025046
reduce bacteria that potentially can cause skin infection.

LOT

Drug Facts (continued)

Warnings

For external use only.

Do not use ■ if allergic to iodine ■ in the eyes

Ask a doctor before use if injuries are
■ deep or puncture wounds ■ serious burn

Stop use and ask a doctor if ■ infection occurs
■ redness, irritation or swelling develops

Keep out of reach of children.
If swallowed, get medical help or contact a Poison Control Center right away

Directions Apply product to skin as needed

Other information ■ 1% titratable iodine
■ Avoid excessive heat ■ Store at room temperature
■ For hospital or professional use only ■ Not made with natural rubber latex

Principal Display Panel - PVP-I 3/4 Ounce Solution Sterile 885-500 Case Label

DUKAL™
CORPORATION

REF 885-500

STERILE

POVIDONE-IODINE
SOLUTION 3/4 OUNCE

For Professional and Hospital Use

Not made with Natural Rubber Latex

500/Case

1/Pack

2

Manufactured For: DUKAL CORPORATION • (631) 656-3800

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Made in China, Hecho en China, Fabriqué en Chine

(01) 40665973025047

PVP-I POUCH FOIL-FOIL

povidone-iodine solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65517-0035
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)	
POTASSIUM IODIDE (UNII: 1C4QK22F9J)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65517-0035-1	500 in 1 CASE	01/31/2018	
1		22 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