

**PREP SOLUTION- 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.*

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**Drug Facts**

**Active Ingredients**

Povidone-Iodine, 10% (equivalent to 1% available iodine)

**Purpose**

Antiseptic

**Use**

Healthcare antiseptic for preparation of the skin prior to surgery

- First aid antiseptic to help prevent infection in minor cuts, scrapes and burns

**Warnings**

**For external use only. Do not use**

- in the eyes
- longer than 1 week unless directed by doctor
- on individuals who are allergic or sensitive to iodine
- or apply over large areas of the body.

**Stop use and ask doctor**

- if irritation and redness develop
- if condition persists for more than 72 hours. In case of deep or puncture wounds, animal bites or serious burns, consult a doctor.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

Clean the affected area

- For preparation of the skin prior to surgery: apply product to the operative site prior to surgery
- For first aid antiseptic: apply a small amount of this product on the area 1 to 3 times daily. May be covered with a sterile bandage. If bandaged, let dry first.

**Other Information**

Protect from freezing. Avoid excessive heat.

**Inactive Ingredient**

Citric Acid, Disodium Phosphate, Glycerin, Polysorbate 80, Sodium Citrate, Water.

**Principal Display Panel - Prep Solution 2 FL OZ Bottle Label**

**DUKAL™**  
CORPORATION

**REORDER**

**871**

**NDC 65517-0023-1**

**Povidone Iodine USP, 10 %**

**Topical Antiseptic Microbicide**

**PREP SOLUTION**

**Solución de preparación**

**Povidona yodada, 10 %**

**Antiséptico antimicrobiano tópico**

**Solution de préparation**

**Polyvidone iodée, 10 %**

**Microbicide antiseptique topique**

DUKAL

Q.V.P

Corporation

**2 FL OZ (59ml)**

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

Ronkonkoma, NY 11779 [www.dukal.com](http://www.dukal.com)

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D04201101



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**871**

Lot # Here

NDC 65517-0023-1

**Povidone Iodine USP, 10%**

**Topical Antiseptic Microbicide**

**PREP SOLUTION**



**Solución de preparación  
Povidona yodada, 10%**

**Antiséptico antimicrobiano tópico**

**Solution de préparation  
Polyvidone iodée, 10 %  
Microbicide antiseptique topique**

**2 FL OZ (59ml)**



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**Drug Facts**

**Active Ingredients**

Povidone-Iodine, 10% (equivalent to 1% available iodine)...Antiseptic

**Purpose**

**Use** Healthcare antiseptic for preparation of the skin prior to surgery • First aid antiseptic to help prevent infection in minor cuts, scrapes and burns

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**Inactive Ingredient** Citric Acid, Disodium Phosphate, Glycerin, Polysorbate 80, Sodium Citrate, Water.



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**Principal Display Panel - Prep Solution 4 FL OZ Bottle Label**

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CORPORATION**

**REORDER**

**872**

**NDC 65517-0023-2**

**Povidone Iodine USP, 10 %**

**Topical Antiseptic Microbicide**

**PREP SOLUTION**

**Solución de preparación**

**Povidona yodada, 10 %**

**Antiséptico antimicrobiano tópico**

**Solution de préparation**

**Polyvidone iodée, 10 %**

**Microbicide antiseptique topique**

**DUKAL**

**Q.V.P**

**Corporation**

4 FL OZ (118ml)

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**REORDER 872**

**Lot # Here**

**Drug Facts**

**Active Ingredients** Povidone-iodine, 10% (equivalent to 1% available iodine)...

**Purpose** Antiseptic

**Use** Healthcare antiseptic for preparation of the skin prior to surgery • First aid antiseptic to help prevent infection in minor cuts, scrapes and burns

**Warnings** For external use only. Do not use • in the eyes • longer than 1 week unless directed by doctor • on individuals who are allergic or sensitive to iodine • or apply over large areas of the body. Stop use and ask doctor • if irritation and redness develop • if condition persists for more than 72 hours. In case of deep or puncture wounds, animal bites or serious burns, consult a doctor. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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**Other Information** Protect from freezing. Avoid excessive heat.

**Inactive Ingredient** Citric Acid, Disodium Phosphate, Glycerin, Polysorbate 80, Sodium Citrate, Water.

**Principal Display Panel - Prep Solution 8 FL OZ Bottle Label**

DUKAL™  
CORPORATION

REORDER

873

NDC 65517-0023-3

Povidone Iodine USP, 10%

Topical Antiseptic Microbicide

PREP SOLUTION

Solución de preparación

Povidona yodada, 10%

Antiséptico antimicrobiano tópico

Solution de préparation

Polyvidone iodée, 10%

Microbicide antiseptique topique

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8 FL OZ (237ml)

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**DUKAL**  
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**873**

Lot # Here

**Drug Facts**

**Active Ingredients** Povidone-Iodine, 10% (equivalent to 1% available iodine)...Antiseptic

**Purpose** Antiseptic

**Use** Healthcare antiseptic for preparation of the skin prior to surgery • First aid antiseptic to help prevent infection in minor cuts, scrapes and burns

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**NDC 65517-0023-3**

**Povidone Iodine USP, 10%**

**Topical Antiseptic Microbicide**

**PREP SOLUTION**

**Solución de preparación Povidona yodada, 10%**

**Antiséptico antimicrobiano tópico**

**Solution de préparation Polyvidone iodée, 10%**

**Microbicide antiseptique topique**

**8 FL OZ (237ml)**

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**Principal Display Panel - Prep Solution 16 FL OZ Bottle Label**

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CORPORATION

**REORDER**

**874**

**NDC 65517-0023-4**

**Povidone Iodine USP, 10%**

**Topical Antiseptic Microbicide**

**PREP SOLUTION**

**Solución de preparación**

**Povidona yodada, 10%**

**Antiséptico antimicrobiano tópico**

**Solution de préparation**

**Polyvidone iodée, 10 %**

**Microbicide antiseptique topique**

DUKAL

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**16 FL OZ (473ml)**

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**REORDER 874**

**NDC 65517-0023-4**

**Povidone Iodine USP, 10%**  
**Topical Antiseptic Microbicide**  
**PREP SOLUTION**

**Solución de preparación Povidona yodada, 10% Antiséptico antimicrobiano tópico**

**Solution de préparation Polyvidone iodée, 10% Microbicide antiseptique topique**

**16 FL OZ (473ml)**

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**Lot # Here**

**Drug Facts**

**Active Ingredients** Povidone-Iodine, 10% (equivalent to 1% available iodine)...Antiseptic

**Purpose** First aid antiseptic to help prevent infection in minor cuts, scrapes and burns

**Use** Healthcare antiseptic for preparation of the skin prior to surgery • First aid antiseptic to help prevent infection in minor cuts, scrapes and burns

**Warnings** For external use only. Do not use • in the eyes • longer than 1 week unless directed by doctor • on individuals who are allergic or sensitive to iodine • or apply over large areas of the body. **Stop use and ask doctor** • if irritation and redness develop • if condition persists for more than 72 hours. In case of deep or puncture wounds, animal bites or serious burns, consult a doctor. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

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**Other Information** Protect from freezing. Avoid excessive heat.

**Inactive Ingredient** Citric Acid, Disodium Phosphate, Glycerin, Polysorbate 80, Sodium Citrate, Water.

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## PREP SOLUTION

povidone-iodine solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65517-0023
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65517-0023-1	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2010	10/26/2020
2	NDC:65517-0023-2	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2010	10/26/2020
3	NDC:65517-0023-3	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2010	05/18/2020
4	NDC:65517-0023-4	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2010	10/23/2020

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/01/2010	10/26/2020

**Labeler** - Dukal Corporation (791014871)

Revised: 9/2018

Dukal Corporation