

POVIDONE-IODINE- povidone-iodine solution
Medline Industries, LP

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.

943 PVP Prep Solution

Active Ingredient

Povidone-Iodine, 10%

(equivalent to 1% available iodine)

Purpose

Antiseptic

Uses

- 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 a doctor
- on individuals who are allergic or sensitive to iodine
- or apply over large areas of the body

Stop use and ask a 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

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) 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

Store at Room Temperature. Protect from freezing. Avoid excessive heat.



Inactive Ingredients

Citric Acid, Disodium Phosphate, Glycerin, Nonylphenol 9, Purified Water, Sodium Citrate

Manufacturing Information

Manufactured for:
Medline Industries, LP
Three Lakes Drive, Northfield, IL 60093 USA
Made in Mexico
www.medline.com
1-800-MEDLINE (633-5463)
REF: 503911
V1 RK22DEG

Package Label

 <p>NDC 53329-943-69</p> <h2>PVP PREP SOLUTION</h2> <p>TOPICAL ANTISEPTIC 10% POVIDONE-IODINE</p> <p>Single use only. Not made with Natural Rubber Latex.</p> <p>3 fl. oz. (88 ml)</p> <p>LOT</p> <p>Exp:</p> <p>REF 503911</p>  <p>(01) 10193489658156</p>	Drug Facts				
	<table><thead><tr><th>Active Ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Povidone-Iodine, 10% (equivalent to 1% available iodine)</td><td>Antiseptic</td></tr></tbody></table>	Active Ingredient	Purpose	Povidone-Iodine, 10% (equivalent to 1% available iodine)	Antiseptic
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4036012					

POVIDONE-IODINE

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-943
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
GLYCERIN (UNII: PDC6A3C0OX)	
N-NONYLPHENOL (MIXED ISOMERS) (UNII: 79F6A2ILP5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-943-69	88 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/04/2016	
2	NDC:53329-943-13	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/04/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/04/2016	

Labeler - Medline Industries, LP (025460908)

Registrant - Medline Industries, LP (025460908)