# 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.

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#### 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**

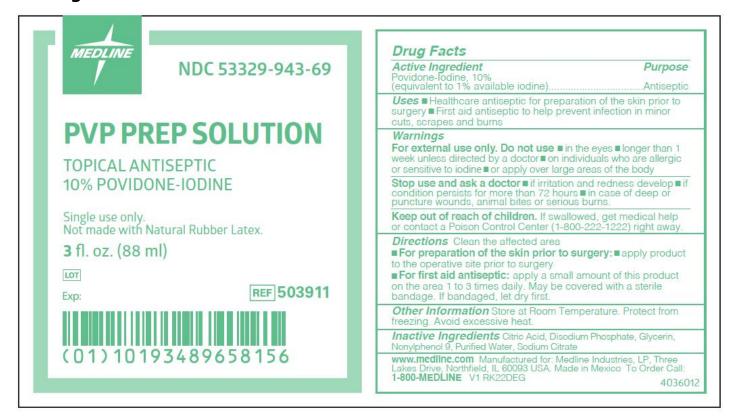
Citric Acid, Disodium Phosphate, Glycerin, Nonylphenol 9, Purified Water, Sodium Citrate

### **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



#### **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	<b>Basis of Strength</b>	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**

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	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		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 Application Number or Monograph Marketing Start Marketing E				
Category	Citation	Date	Date	
OTC monograph not final	part333E	11/04/2016		

# Labeler - Medline Industries, LP (025460908)

# Registrant - Medline Industries, LP (025460908)

Revised: 12/2022 Medline Industries, LP