POVIDONE IODINE- povidone iodine solution Major Pharmaceuticals

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.

Povidone Iodine Prep

Active ingredient

Active Ingredient	Purpose	
Povidone Iodine 10% v/v	Antiseptic	

Uses

- First aid antiseptic to help prevent infection in minor cuts, scrapes and burns.
- Healthcare antiseptic for preparation of the skin prior to surgery.
- Antiseptic cleanser for preparation of skin prior to an infection.

Warnings

• FOR EXTERNAL USE ONLY

Do not use

- As a first aid antiseptic for more than 1 week unless directed by a doctor.
- In the eyes.
- Over large areas of the body.
- On individuals who are allergic or sensitive to iodine.

Ask a doctor before use if you have

- Deep puncture wounds
- Animal bites
- Serious burns

Stop Use

- If irritation and redness develop
- If condition persists for more than 72 hours, consult a physician.

Keep Out Of Reach Of Children

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

Directions

As a first aid antiseptic

• clean affected area

- apply a small amount of this product to the area1 to 3 times daily
- may be covered with a sterile bandage, if bandaged let dry.

For preoperative patient skin preparation

- clean area
- apply to operative site prior to surgery using the applicator

NDC 0904-1103-09

Inactive Ingredient

- citric acid
- glycerin
- sodium citrate
- tween 80
- disodium phosphate
- purified Water

For use as an

- first aid antiseptic
- pre-operative skin preperation

Principal Display Panel

Povidone Iodine Topical Solution

(10% Povidone-Iodine Solution, USP)

TOPICAL ANTISEPTIC

Helps prevent infection in cuts, scrapes, burns and minor skin wounds

A Primary Hospital Antiseptic

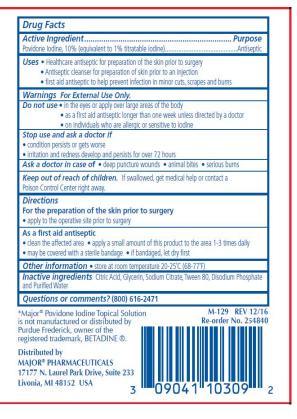
Compare to active ingredient in Betadine®*

8 fl oz (236 mL)

POVIDONE IODINE

povidone iodine solution

Product Information



Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:0904-1103	
Route of Administra	tion	TOPICAL				
Active Ingredient	t/Active Moi	ety				
Ingredient Name Basis of Streng			th Strength			
PO VIDO NE-IO DINE (U	UNII: 85H0 HZU9	9M) (IODINE - UNII:9679TC07X	4)	IO DINE	100 mg in 1 mL	
Inactive Ingradia	nto					
Inactive Ingredients Ingredient Name					Strength	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				Strength		
WATER (UNII: 059QF0K00R)						
GLYCERIN (UNII: PDC6A3C0OX)						
SODIUM CITRATE (UNII: 1Q73Q2JULR)						
POLYSORBATE 80 (UNII: 6OZP39ZG8H)						
SO DIUM PHO SPHATE						
Packaging						
# Item Code		Package Description	Ν	Aarketing Start Date	Marketing End Date	
1 NDC:0904-1103-09	237 mL in 1 BO	TLE; Type 0: Not a Combination	n Product 12	2/21/2011		
Marketing Information						
maine ung inte						
	Applicatio	on Number or Monograph Ci	tation M	Iarketing Start Date	Marketing End Date	
Marketing Category OTC monograph final	y Applicatio part333C	on Number or Monograph Ci		Iarketing Start Date '21/2011	Marketing End Date	

Labeler - Major Pharmaceuticals (191427277)

Revised: 8/2019

Major Pharmaceuticals