

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

Povidone Iodine 10% v/v

Purpose

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 area 1 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

Inactive Ingredient

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

For use as an

- first aid antiseptic
- pre-operative skin preparation

Principal Display Panel

NDC 0904-1103-09																																																	
																																																	
<h1>Povidone Iodine Topical Solution</h1> <p>(10% Povidone-Iodine Solution, USP)</p>																																																	
<h2>TOPICAL ANTISEPTIC</h2>																																																	
<p><i>Helps prevent infection in cuts, scrapes, burns and minor skin wounds</i></p>																																																	
<h3>A Primary Hospital Antiseptic</h3>																																																	
<p><i>Compare to active ingredient in Betadine®*</i></p>																																																	
<p>8 fl oz (236 mL)</p>																																																	
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<p>*Major® Povidone Iodine Topical Solution is not manufactured or distributed by Purdue Frederick, owner of the registered trademark, BETADINE®.</p> <p>Distributed by MAJOR® PHARMACEUTICALS 17177 N. Laurel Park Drive, Suite 233 Livonia, MI 48152 USA</p>	<p>M-129 REV 12/16 Re-order No. 254840</p>  <p>3 09041 10309 2</p>																																																

POVIDONE IODINE

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-1103	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)		IODINE	100 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
SODIUM PHOSPHATE (UNII: SE337SVY37)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-1103-09	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2011	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	12/21/2011		

Labeler - Major Pharmaceuticals (191427277)

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