

POVIDONE IODINE- povidone iodine solution

Major Pharmaceuticals

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



**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)

Drug Facts	
Active Ingredient	Purpose
Povidone Iodine, 10% (equivalent to 1% titratable iodine).....	Antiseptic
Uses • Healthcare antiseptic for preparation of the skin prior to surgery • Antiseptic cleanser for preparation of skin prior to an injection • first aid antiseptic to help prevent infection in minor cuts, scrapes and burns	
Warnings For External Use Only.	
Do not use • in the eyes or apply over large areas of the body • as a first aid antiseptic longer than one week unless directed by a doctor • on individuals who are allergic or sensitive to iodine	
Stop use and ask a doctor if • condition persists or gets worse • irritation and redness develop and persists for over 72 hours	
Ask a doctor in case of • deep puncture wounds • animal bites • serious burns	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions For the preparation of the skin prior to surgery • apply to the operative site prior to surgery	
As a first aid antiseptic • clean the affected area • apply a small amount of this product to the area 1-3 times daily • may be covered with a sterile bandage • if bandaged, let dry first.	
Other information • store at room temperature 20-25°C (68-77°F)	
Inactive ingredients Citric Acid, Glycerin, Sodium Citrate, Tween 80, Disodium Phosphate and Purified Water	
Questions or comments? (800) 616-2471	

*Major® Povidone Iodine Topical Solution is not manufactured or distributed by Purdue Frederick, owner of the registered trademark, BETADINE®.

M-129 REV 12/16
Re-order No. 254840

Distributed by
MAJOR® PHARMACEUTICALS
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POVIDONE IODINE

povidone iodine solution

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: PDC6A3C00X)	
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 Drug	M003	12/21/2011	

Labeler - Major Pharmaceuticals (191427277)

Revised: 11/2023

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