POVIDONE IODINE- povidone iodine solution Major Pharmaceuticals

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)

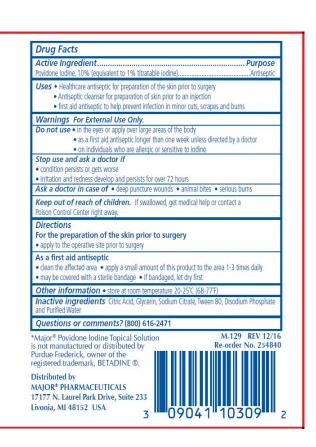
TOPICAL ANTISEPTIC

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 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

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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

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	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
			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 Major Pharmaceuticals