POVIDONE IODINE PREP- povidone iodine solution Sion Biotext Medical Ltd

Drug Facts

Active ingredient

Povidone-Iodine 10% (equivalent to 1% titrable Iodine)

Purpose

Antiseptic

Uses

- First Aid for minor cuts, scrapes, and burns (helps prevent infection)
- Preoperative skin prep (reduces bacteria)

Warning

For external use only.

Do Not Use:

- In eyes
- More than week (unless advised by a doctor)
- On those allergic/senstiive to iodine
- Over large body areas

Ask a doctor before use if:

- Deep or puncure wounds.
- Animal Bites
- Serious wounds

Stop use and ask a doctor if:

- Irritation or redness appears
- Condition lasts more than 72 hours

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center immediately

Directions

As a first aid antiseptic:

- Clean affected area
- Apply a fingertip-sized amount 1-3 tmes daily
- Cover with a sterile bandage if desired (allow to dry first)

For preoperative patient skin preparation:

- Clean area
- Apply before surgery
- Let dry at least 2 minutes before draping
- Remove soiled underdrapes
- Avoid pooling

Other Information

- Store at room temperature 20-25° C (68-77°F)
- Avoid excessive heat
- Not made with natural rubber latex

Inactive Ingredients

Citric acid, dibasic sodium phosphate, glycerin, polysorbate 80 (tween 80), sodium citrate, water.

NDC 68786-010-89

SIONBIOTEXT

Prep Solution Topical Antiseptic Microbicide

10% POVIDONE IODINE

NET CONTENT

3 fl.oz. (89 ml)

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Manufactured for:

Sion Biotext Medical Ltd. 3 Eshel St.. Sapirim Industrial Park, 8701002, Sderot, ISRAEL Tel: 972-8-6898650 Fax: 972-8-6898572 Email: sales@sn-medical.com



POVIDONE IODINE PREP

povidone iodine solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68786-010

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4) **IODINE** 10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Packaging

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# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:68786-010-	89 mL in 1 PACKET; Type 0: Not a Combination	05/06/2025	

89	Product	05/00/2025			
	Marketing Information				
Marketing I					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M003	05/06/2025			

Labeler - Sion Biotext Medical Ltd (532775194)

Registrant - Sion Biotext Medical Ltd (532775194)

Revised: 5/2025 Sion Biotext Medical Ltd