MEDPRIDE PREP SOLUTION TOPICAL ANTISEPTIC MICROBICIDE- povidoneiodine solution Shield Line LLC

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.

Medpride Prep Solution Topical Antiseptic Microbicide

Active Ingredient

Povidone Iodine, 10% (equivalent to 1% available Iodine)

Purpose

Antiseptic

Uses

- Health-care antiseptic for preparation of the skin prior to surgery
- First aid antiseptic to help prevent infection in minor cuts, scrapes and burns

Warnings

For External Use Only

Do not use

- In eyes
- As a first antiseptic longer than one week
- On individuals who are allergic or sensitive to iodine
- Apply over large areas of body

Discontinue use and call your doctor if

- Irritation and redness develop and persists for more than 72 hours
- Condition persists or get worse

Ask your doctor in case of

- Deep or 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 preparation of the skin prior to surgery:

• Apply product to the operative site prior to surgery

As a first aid antiseptic:

- Clean the affected area
- Apply a small amount of this product on the area 1-3 times daily
- May be covered with a sterile bandage
- If bandaged, let dry first

Inactive ingredients

Citric Acid, Sodium Citrate, Glycerin, Tween 80, Disodium Phosphate, Purified Water

Principal Display Panel

NDC: 52410-4114-6



Prep Solution Povidone Iodine 10%

- Topical Antiseptic Microbicide
- Promptly kills germs in: Cuts, Burns, Scrapes, Minor Skin Wounds

Drug Facts

Active ingredient

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Directions For preparation of the skin prior to surgery: apply product to the operative site prior to surgery

As a first aid antiseptic: Apply a small amount of this product on 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, Sodium Citrate, Glycerin, Tween 80, Disodium Phosphate, Purified Water



Manufactured for: Shield Line LLC, Hackensack, NJ 07601

Made in Mexico 10-41146MP-02

Reorder No: MPR-41146

LOT



1 Gallon (3.78 Ltr)



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povidone-iodine solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:52410-4114

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4) IODINE 100 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)				
POLYSORBATE 80 (UNII: 60ZP39ZG8H)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)				
WATER (UNII: 059QF0KO0R)				

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:52410- 4114-5	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/13/2019			
2	NDC:52410- 4114-6	3785 mL in 1 JUG; Type 0: Not a Combination Product	05/13/2019			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	05/13/2019		

Labeler - Shield Line LLC (078518916)

Revised: 4/2023 Shield Line LLC