

POVIDONE IODINE PREP - povidone iodine solution
Cardinal Health

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.

Drug Facts

Active ingredient

Povidone Iodine 10%

(equivalent to 1% titratable iodine)

Purpose

Antiseptic/First Aid Antiseptic

Uses

- First aid to help prevent skin infection in minor cuts, scrapes, and burns
- For preparation of the skin prior to skin surgery
- Helps to reduce bacteria that can potentially cause skin infection

Warnings

For External Use Only.

Do not use

As a first aid antiseptic

- Do not use in the eyes or apply over large areas of the body
- In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor
- Stop use and consult a doctor if the condition persists or gets worse
- Do not use longer than 1 week unless directed by a doctor

For preoperative patient skin preparation

- Do not use in the eyes
- Discontinue use if irritation and redness develop
- If condition persists for more than 72 hours, consult a doctor

Keep out of reach of children.

- If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Clean the affected area.

For preparation of skin prior to surgery

- Apply product to the operative site prior to surgery

For 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

- Protect from freezing
- Avoid excessive heat

Inactive Ingredients:

Citric Acid, Disodium Phosphate, Nonoxynol-9, Sodium Hydroxide, Water

Principal Display Panel

Povidone-Iodine Prep Solution

Povidone-Iodine 10%

single use only

Cardinal Health

Net Wt. 0.75 fl oz (22.2 mL)

NDC 63517-132-01

NDC 63517-132-01

Povidone-Iodine Prep Solution

Povidone-Iodine 10%
single use only



Net Wt 0.75 fl oz (22.2mL)

Drug Facts

Active ingredient
Povidone-Iodine USP 10% (Equivalent to 1% Iodine solution)

Purpose
Antiseptic / Disinfectant / Sterilant

Uses - First aid to help prevent skin infection in minor cuts, scrapes, and burns - For preparation of the skin prior to surgery - Helps to reduce bacteria that can potentially cause skin infection

Warnings
For external use only.
As a first aid antiseptic:
- Do not use on deep or large wounds or on large areas of the body.
- In case of severe irritation, swelling, small blisters, or serious burns, consult a doctor.
- Stop use and consult a doctor if the condition persists or gets worse.
- Do not use longer than 1 week unless directed by a doctor.
For preparative patient skin preparation
- Do not use in the eyes.
- Do not use on the face, neck, and sensitive skin.
- If condition persists for more than 72 hours, consult a doctor.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions Clean the affected area.
For preparation of the skin prior to surgery
- Apply product to the operative site prior to surgery.
- For use on the skin prior to surgery:
- 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 - Protect from freezing.
- Avoid excessive heat.

Inactive ingredients Citric Acid, Disodium Phosphate, Benzoyl Peroxide, Sodium Hydroxide, Water.

For Medical, Professional and Hospital Use
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POVIDONE IODINE PREP

povidone iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63517-132
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0K00R)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

SODIUM HYDRO XIDE (UNII: 55X04QC32I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63517-132-01	500 in 1 CASE		
1		22.2 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	08/26/2015	

Labeler - Cardinal Health (097537435)

Revised: 8/2015

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