

POVIDINE IODINE - povidine iodine swab
Dynarex Corporation

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.

Povidone Iodine Prep Pad

Section Text

Active Ingredient

Povidone Iodine 10% v/v

Purpose

Antiseptic

Uses:

Section Text

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

Warnings:

Section Text

- **FOR EXTERNAL USE ONLY**

Do not use:

Section Text

- As a first aid antiseptic for more than 1 week.
- In the eyes.
- Over large areas of the body.

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:

Tear at notch, remove applicator, use only once.

As a first aid antiseptic

- clean affected area
- apply 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

Other information:

Store at room temperature.

Avoid excessive heat

Principal Display Panel

Principal Display Panel



Drug Facts	
Active ingredient Povidone iodine 10%.....	Purpose Antiseptic
Uses • first aid antiseptic to help prevent skin infection in minor cuts, scrapes, and burns . for preparation of the skin prior to surgery • helps reduce bacteria that can potentially cause skin infection	
Warnings • For external use only Do not use . in the eyes . as a first aid antiseptic for more than 1 week . over large areas of the body Ask a doctor before use if you have . deep or puncture wounds . animal bites . serious wounds Stop use and ask doctor if . condition worsens or persists for more than 72 hours . irritation and redness develops	

Drug Facts (continued)
Keep out of reach of children . if swallowed, get medical help or contact a Poison Control Center right away
Directions • tear at notch . remove applicator . use only once As a first aid antiseptic • clean affected area . apply 1 to 3 times daily . may be covered with a sterile bandage . if bandaged let dry first For preoperative patient skin preparation • clean area . apply to operative site prior to surgery using applicator
Other Information • store at room temperature . avoid excessive heat
Inactive Ingredients nonoxynol-9, water

POVIDINE IODINE

povidine iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-140
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IO DINE (UNII: 85H0HZU99M) (POVIDONE-IODINE - UNII:85H0HZU99M)	POVIDONE-IODINE	10 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength

NONOXYNOL-9 (UNII: 48Q180SH9T)

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-140-01	10 in 1 CASE		
1		100 in 1 BOX		
1		.3 mL in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333	05/10/2010	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Establishment

Name	Address	ID/FEI	Business Operations
Sion Biotext Medical Ltd		532775194	manufacture

Revised: 5/2010

Dynarex Corporation