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.

Section Text

Active Ingredient

Povidone Iodine 10% v/v

Antiseptic

Purpose

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:

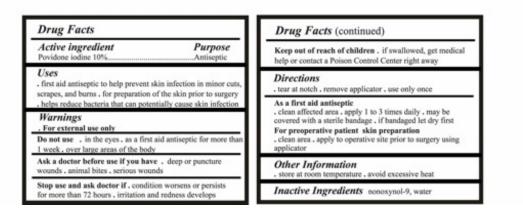
Store at room temperature.

Avoid excessive heat

Principal Display Panel

Principal Display Panel





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 Basis of Strength Ingredient** Name Strength **POVIDONE-IODINE** (UNII: 85H0 HZU99M) (POVIDONE-IODINE - UNII:85H0 HZU99M) POVIDONE-IODINE 10 mL in 100 mL **Inactive Ingredients Ingredient Name** Strength

NONO	XYNOL-9 (UNII: 4	18Q180SH9T)				
WATE	R (UNII: 059QF0K	O0R)				
Packa	aging					
#	Item Code	Package Description	Marketin	ng Start Date	Ma	arketing End Date
1 NDC	:67777-140-01	10 in 1 CASE				
1		100 in 1 BOX				
1		.3 mL in 1 POUCH				
	1. .					
Mar	keting Info	rmation				
Marketing Category		Application Number or Monograph Citation		Marketing Start Date		Marketing End Date
OTC monograph final		part333		0 5/10/20 10		

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