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 Swabstick

Section Text

Active Ingredient Purpose

Povidone Iodine 10% v/v Antiseptic

Purpose:

Purpose:

- 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:

- 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 Povidone iodine:

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

For use as an

- first aid antiseptic
- pre-operative skin preperation

Inactive Ingredients

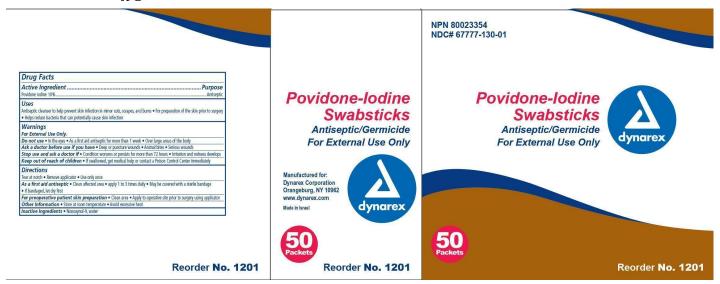
Inactive ingredients: nonoxynol-9, water

Principal Display Panel

Principal Display Panel

Povidone Iodine Swabsticks 1201 & 1202

Povidone iodine.jpg



povidine iodine swab

Product	Infor	mation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:67777-130

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
PO VIDO NE-IO DINE (UNII: 85H0 HZU99 M) (IO DINE - UNII:9679 TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients

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	Ingredient Name	Strength
	NONOXYNOL-9 (UNII: 48Q180SH9T)	

WATER (UNII: 059QF0KO0R)

Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-130-01	50 in 1 BOX		
1		0.3 mL in 1 PACKET		
2	NDC:67777-130-02	25 in 1 BOX		
2		0.9 mL in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	05/10/2010	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Establishment

Little				
	Name	Address	ID/FEI	Business Operations
	Sion Biotext Medical Ltd		532775194	manufacture(67777-130)

Revised: 12/2013 Dynarex Corporation