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 Gel Swabstick

Active Ingredient Purpose Povidone Iodine 10% v/v 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 infections.

Warnings:

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 Gel Swabstick:

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:

Sterile

Store at room temperature.

Avoid excessive heat

For use as an

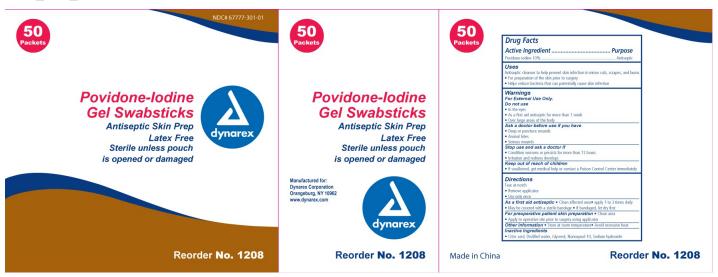
- first aid antiseptic
- pre-operative skin preperation

Inactive Ingredients

Inactive ingredients: citric acid, glycerol, nonoxynol-10, sodium hydroxide, water

Principal Display Panel

PVP_Gel_Swabstick



POVIDINE IODINE

povidine iodine swab

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-301	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PO VIDO NE-IO DINE (UNII: 85H0 HZU99M) (PO VIDO NE-IO DINE - UNII:85H0 HZU99M)	POVIDONE-IODINE	10 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
NONOXYNOL-10 (UNII: K7O76887AP)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NI	DC:67777-301-01	10 in 1 CASE		
1		50 in 1 BOX		
1		1 in 1 POUCH		
1		.3 mL in 1 POUCH		
2 NI	DC:67777-301-02	10 in 1 CASE		
2		25 in 1 BOX		
2		3 in 1 POUCH		
2		.9 mL in 1 POUCH		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	02/10/2012		

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

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