POVIDINE IODINE - povidine iodine solution Chain Drug Consortium, LLC

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

Active Ingredient Purpose

Povidone Iodine 10% v/v Antiseptic

Uses: povidone iodine prep

povidone iodine prep

- 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:

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

Inactive Ingredient:

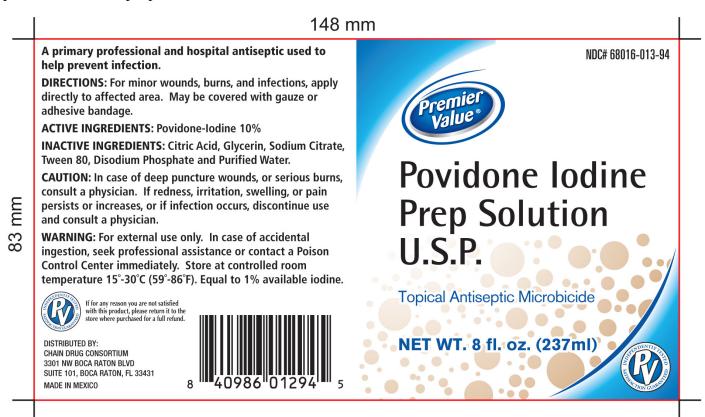
Inactive Ingredient: Citric Acid, Glycerin, Sodium Citrate, Tween 80, Disodium Phosphate, Water

For use as an

- first aid antiseptic
- pre-operative skin preperation

Principal Display Panel

povidone_iodine_prep



POVIDINE IODINE

povidine iodine solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-013	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PO VIDO NE-IO DINE (UNII: 85H0 HZU99 M) (PO VIDO NE-IO DINE - UNII:85H0 HZU99 M)	POVIDONE-IODINE	10 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
SO DIUM CITRATE (UNII: 1Q73Q2JULR)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
SODIUM PHO SPHATE (UNII: SE337SVY37)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:68016-013-94	6 in 1 CASE				
1		236 mL in 1 BOTTLE				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	03/17/2011		

Labeler - Chain Drug Consortium, LLC (101668460)

Revised: 5/2011 Chain Drug Consortium, LLC