POVIDONE IODINE PREP- povidone-iodine patch
MCL Enterprises

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

Drug Facts

Active Ingredient

Povidone-Iodine 10% (w/w) (equivalent to 1 % titratable iodine)

Purpose

Antiseptic

Use:
- For preparation of the skin prior to surgery
- First aid antiseptic to help prevent infection in scrapes, minor cuts and burns

Warnings:
- **For external use only**

Keep out of reach of children.
- If swallowed, get medical help or contact a Poison Control Center right away.

Do not use:
- in the eyes or apply over large areas of the body
- longer than 1 week unless directed by a doctor
- on individuals who are sensitive or allergic to iodine

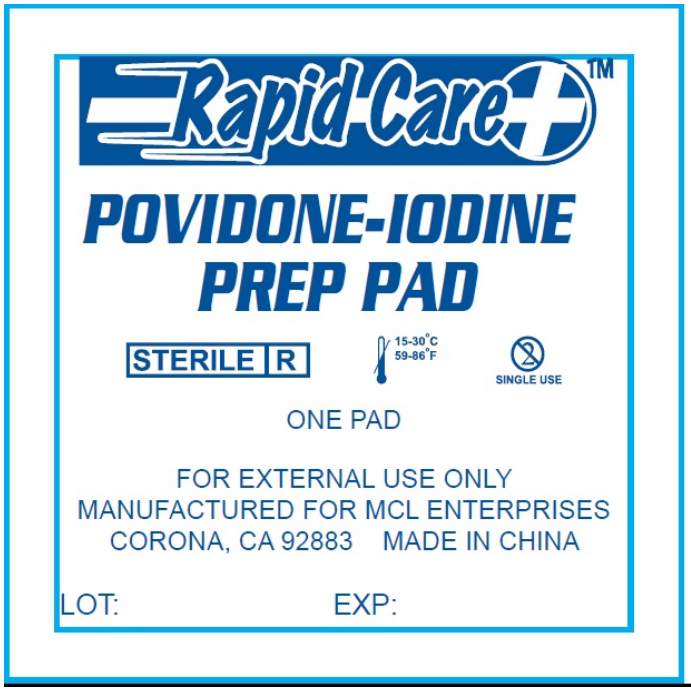
Stop use and ask a doctor if:
- if irritation and redness develop.
- condition persists more than 72 hours
- in case of deep or puncture wounds, animal bites or serious burns

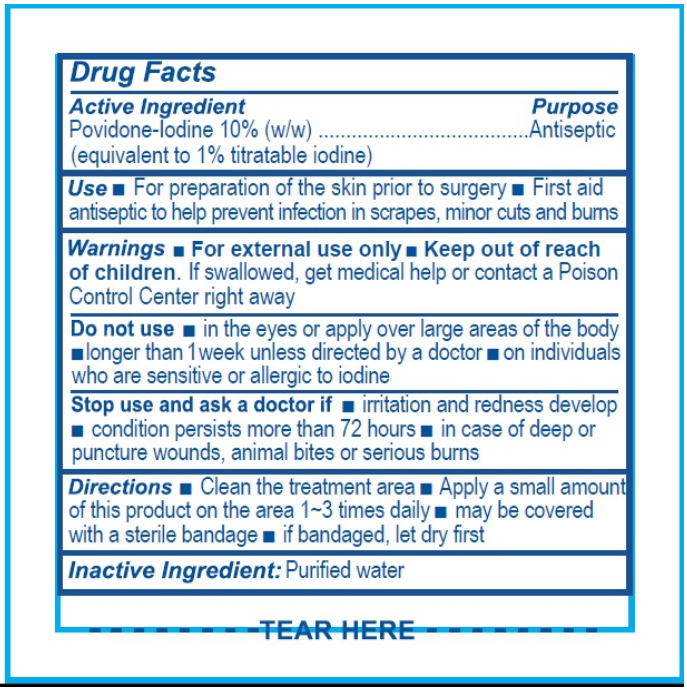
Directions:
- Clean the treatment area
- Apply a small amout of this product on the area 1~3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first

Inactive Ingredient:

Purified Water

Package Labeling:





POVIDONE IODINE PREP

povidone-iodine patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71622-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	100 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71622-003-00	1 in 1 POUCH	07/25/2017	
1		0.45 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part333E	07/25/2017	

Labeler - MCL Enterprises (784754173)

Revised: 12/2017 MCL Enterprises