POVIDONE IODINE PREP PADS- povidone iodine prep pads cloth
Custom Kits Company Inc

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%

Purpose

Antiseptic

Uses

Antiseptic cleanser to help prevent skin infection in minor cuts, scrapes and burns.

For preparation of the skin prior to surgery

Helps reduct bacteria that can potentially cause skin infection

Warnings

For External Use Only

Do Not Use

In the eyes

As a first aid antiseptic for more than 1 week

Over large areas of the body

Ask doctor before use if you have

Deep or puncuture wounds

Animal bites

Serious wounds

Stop Use and ask doctor if

Condition worsens or persists for more than 72 hours

Irritation and rednes develops

Keep Out of the reach of Children

If swallowed, get medical help or contact a Poson Control Center immediately

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

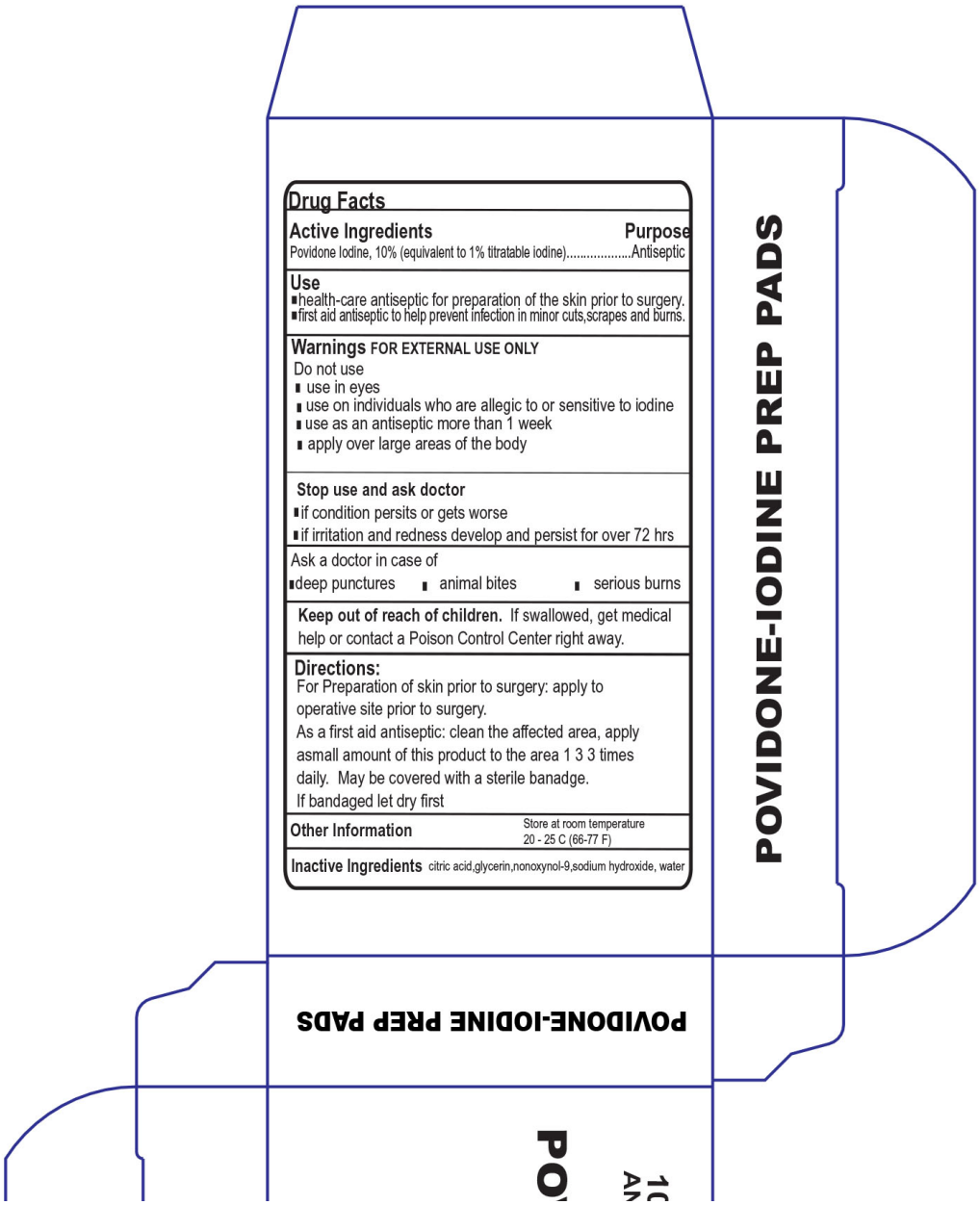
If bandaged let dry first

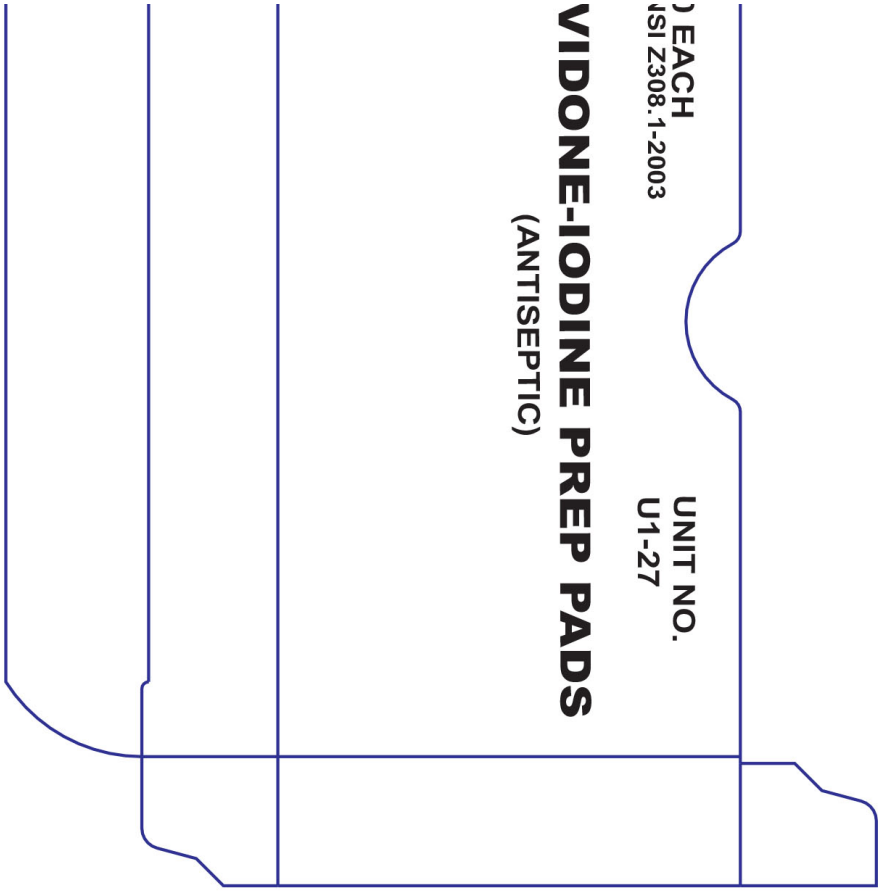
Store at room temperature

Avoid excessive heat

Inactive ingredient

nonoxynol-9, water





POVIDONE IODINE PREP PADS

povidone iodine prep pads cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68183-119
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68183-119-01	10 mL in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	10/21/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	10/21/2015	

Labeler - Custom Kits Company Inc (928643712)

Establishment

Name	Address	ID/FEI	Business Operations
Dynarex		812771980	manufacture(68183-119)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Kits Company Inc		928643712	relabel(68183-119) , repack(68183-119)

Revised: 1/2020 Custom Kits Company Inc