POVIDONE-IODINE PREP PAD- povidone-iodine swab Davemed Healthcare Co., Ltd

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

Active Ingredient

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

Purpose

Antiseptic

Use

Antiseptic for preparation of the skin. Non-sterile Solution Applicator is sterile if package is intact

Warnings

For external use only.

Discontinue use if irritation and redness develop. Keep out of reach of Children.

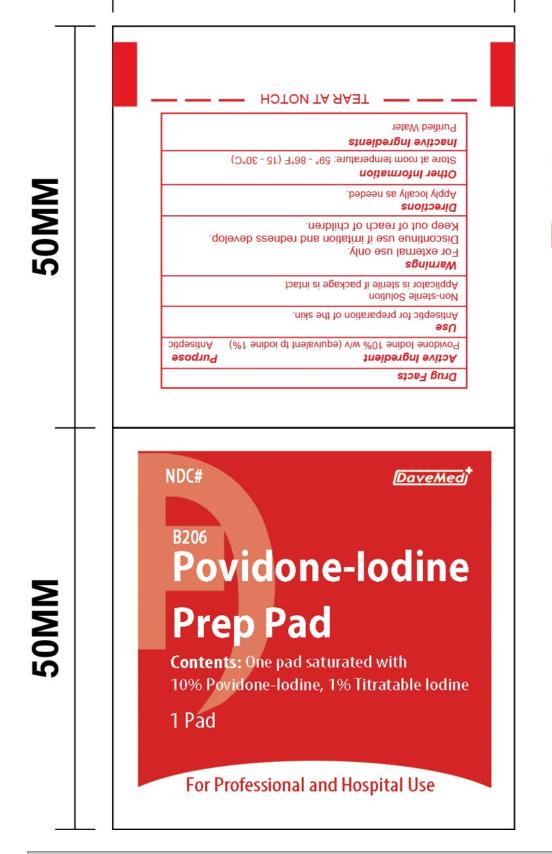
Directions

Apply locally as needed.

Inactive ingredients

Purified Water

50MM



B206



POVIDONE-IODINE PREP PAD

povidone-iodine swab

Product Informati	on								
Product Type	HUMAN OTC DRUG Item Code (Sou			Code (Sour	rce)		NDC:70897-006		
Route of Administrati	ion	TOPICAL							
Active Ingredient/	Active Moi	etv							
Ingredient Name						Basis of Streng		Strength	
PO VIDO NE-IO DINE (UNII: 85H0 HZU99 M) (IO DINE - UNII:9679 TC07X4)					IODINE 0.1 mg			0.1 mg	
Inactive Ingradian									
Inactive Ingredients									
		ngredient Name				Strength			
WATER (UNII: 059QF0KO0R)									
Packaging									
# Item Code		Package Description Marketin			g Start Date		Marketing End Date		
1 NDC:70897-006-01	1 in 1 PACKET	; Type 0: Not a Combination Pro	duct	0 1/24/20 19					
Marketing Information									
Marketing Category	Applicatio	on Number or Monograph Ci	tation	Marketi	ng St	art Date	Marketi	ng End Date	
OTC monograph final	part333C		0 1/24/20			4/2019			

Labeler - Davemed Healthcare Co., Ltd (529128716)

Establishment

Name	Address	ID/FEI	Business Operations
Davemed Healthcare Co., Ltd		529128716	manufacture(70897-006)

Revised: 1/2019

Davemed Healthcare Co., Ltd