

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

50MM

50MM

TEAR AT NOTCH

Drug Facts
Active Ingredient Povidone Iodine 10% w/v (equivalent to Iodine 1%) 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.
Other Information Store at room temperature: 59° - 86°F (15 - 30°C)
Inactive Ingredients Purified Water

B206

 PANTONE:1797

DaveMed⁺

NDC#

B206

Povidone-Iodine Prep Pad

Contents: One pad saturated with
10% Povidone-Iodine, 1% Titratable Iodine

1 Pad

For Professional and Hospital Use

POVIDONE-IODINE PREP PAD
povidone-iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70897-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	0.1 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70897-006-01	1 in 1 PACKET; Type 0: Not a Combination Product	01/24/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/24/2019	

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