

POVIDONE-IODINE PREP PAD MEDIUM STERILE- povidone-iodine pad cloth
Zhejiang Xingheng Medical Supplies 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.

81636-006 Povidone-Iodine Pad

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

Antiseptic

For external use only.

- Clean the affected area
- Apply product on the area 1-3times daily and discard
- May be covered with a sterile bandage when dry

Do not use:

- in the eyes.
- apply over large areas of the body.
- on individuals who are allergic or sensitive to iodine.

Stop use and consult a doctor

- if the condition persists or gets worse.
- for use longer than 1week.

Ask a doctor in case of deep or puncture wounds, animal bites & serious burns.

If swallowed, get medical help or contact Poison Control Center right away.

Sodium Bicarbonate, Polysorbate 20, Polyethylene Glycol 400, Potassium Iodate, Water

Apply topically as needed to cleanse intendend area□

Apply the product to the skin, take the injection or puncture site as the center, slowly rotate from the inside to the outside, and gradually apply the product for two times, the disinfection area should be more than 5cmx5cm, and the action time should be1min.

Use for preparation of skin prior to injection□apply the product to the skin, take the injection or puncture site as the center, slowly rotate from the inside to the outside, and gradually apply the product for two times, the disinfection area should be more than 5cmx5cm, and the action time should be 1min.Please clean before disinfection.

5CM

5CM

NDC: XXXXX-XXXX-X

Povidone Iodine Prep Pad

10% Povidone Iodine USP
For Professional and Hospital Use

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Zhejiang Xingheng Medical Supplies Co.,Ltd
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Yuetan Villiage, Ditian Fuction, Jindong Zone, Jinhua,
Zhejiang (Inside Of Jinhua Quanlei Toy Co.,Ltd)

Drug Facts

Active ingredient

Povidone Iodine USP,10% w/w
(equivalent to 1% titratable iodine)
Use: First aid to help prevent infe
and burns

Warnings For external use only

- apply over large areas of the bc
are allergic or sensitive to iodine.
- **doctor** • if the condition persists
than 1week. • **Ask a doctor** in ca
wounds,animal bites serious burn
children. If swallowed, get medic
Control Center right away.

Directions • Clean the affected
area 1-3times daily and discard •
bandage when dry

Inactive ingredients Sodium Bic
Polyethylene Glycol 400,Potassiu

TEAR

LOT:

MFD:

POVIDONE-IODINE PREP PAD MEDIUM STERILE

povidone-iodine pad cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81636-006
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 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	0.01 g in 100 g
POTASSIUM IODATE (UNII: I139E44NHL)	0.01 g in 100 g
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.01 g in 100 g
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.01 g in 100 g
WATER (UNII: 059QF0KO0R)	89.96 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81636-006-01	100 in 1 CARTON	08/16/2022	
1		100 in 1 BOX		
1		5.5 g in 1 POUCH; 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	part333A	08/16/2022	

Labeler - Zhejiang Xingheng Medical Supplies Co., Ltd. (554554581)

Registrant - Zhejiang Xingheng Medical Supplies Co., Ltd. (554554581)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Xingheng Medical Supplies Co., Ltd.		554554581	manufacture(81636-006)

Revised: 8/2022

Zhejiang Xingheng Medical Supplies Co., Ltd.