

ZONSEN POVIDONE-IODINE PREP PAD- povidone-iodine swab
Wuhan Zonsen Medical Products 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.

Zonsen Povidone-Iodine Prep Pad

Drug Facts

Active Ingredients

Povidone-Iodine 10% w/w (1% available iodine)

Purpose

Antiseptic

Use

- Healthcare antiseptic for preparation of the skin prior to surgery.
- First aid antiseptic to help prevent infection in minor cuts, scrapes and burns.

Warnings

- For external use only.

Do not use

- in the eyes.
- longer than 1 week unless directed by a doctor.
- on individuals who are allergic or sensitive to iodine.
- or apply over large areas of the body.

Stop use and ask a doctor if

- If irritation and redness develop.
- condition persist for more than 72 hours.
- In case of deep or puncture wounds, animal bites or serious burns, consult a doctor.

Keep out of reach of children.

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

Directions

- Clean the affected area.
- For preparation of the skin prior to surgery: apply product to the operative site prior to surgery
- For first aid antiseptic: apply a small amount of this product on the area 1 to 3 times daily. May be covered with a sterile bandage. If bandaged, let dry first.

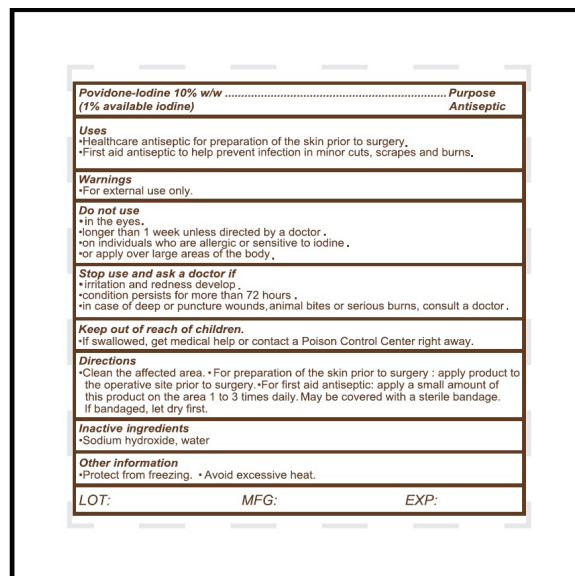
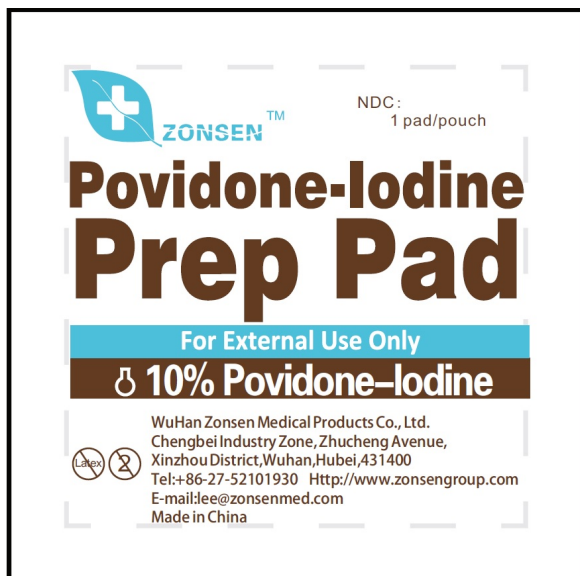
Inactive Ingredients:

Sodium hydroxide, water

Other information

- Protect from freezing
- Avoid excessive heat.

Package Labeling:



ZONSEN POVIDONE-IODINE PREP PAD

povidone-iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72932-003
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 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72932-003-00	1 in 1 POUCH	04/01/2019	
1		0.45 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/01/2019	

Labeler - Wuhan Zonsen Medical Products Co., Ltd. (554474517)

Establishment

Name	Address	ID/FEI	Business Operations
Wuhan Zonsen Medical Products Co., Ltd.		554474517	manufacture(72932-003)

Revised: 5/2019

Wuhan Zonsen Medical Products Co., Ltd.