

POVIDONE-IODINE PREP PAD - povidone-iodine swab
Jiangsu Province JianErKang Medical Dressing 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.

Drug Facts

Cat.40000-020 NDC 34645-4002-1 Qty. 1ea

Povidone-Iodine Prep Pad

Antiseptic/Germicide, Medium*For Single Use Only

Saturated with a 10% povidone-iodine solution

equivalent to 1% titratable iodine

For External Use Only

Distributed by:

Cardinal Health

Dublin, OH 43017 USA

Made in China

Active ingredient

Povidone Iodine USP, 10% w/v

(equivalent to 1% titratable iodine)

Purpose

First Aid

Antiseptic

Use

First aid to help prevent infection in minor cuts, scrapes, and burns

Warnings

For external use only.

Do not * use in the eyes * apply over large areas of the body

* use 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 1 week

Ask doctor

in case of deep or puncture wounds, animal bites, serious burns.

Keep out of reach of children.

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

Directions

Clean the affected area

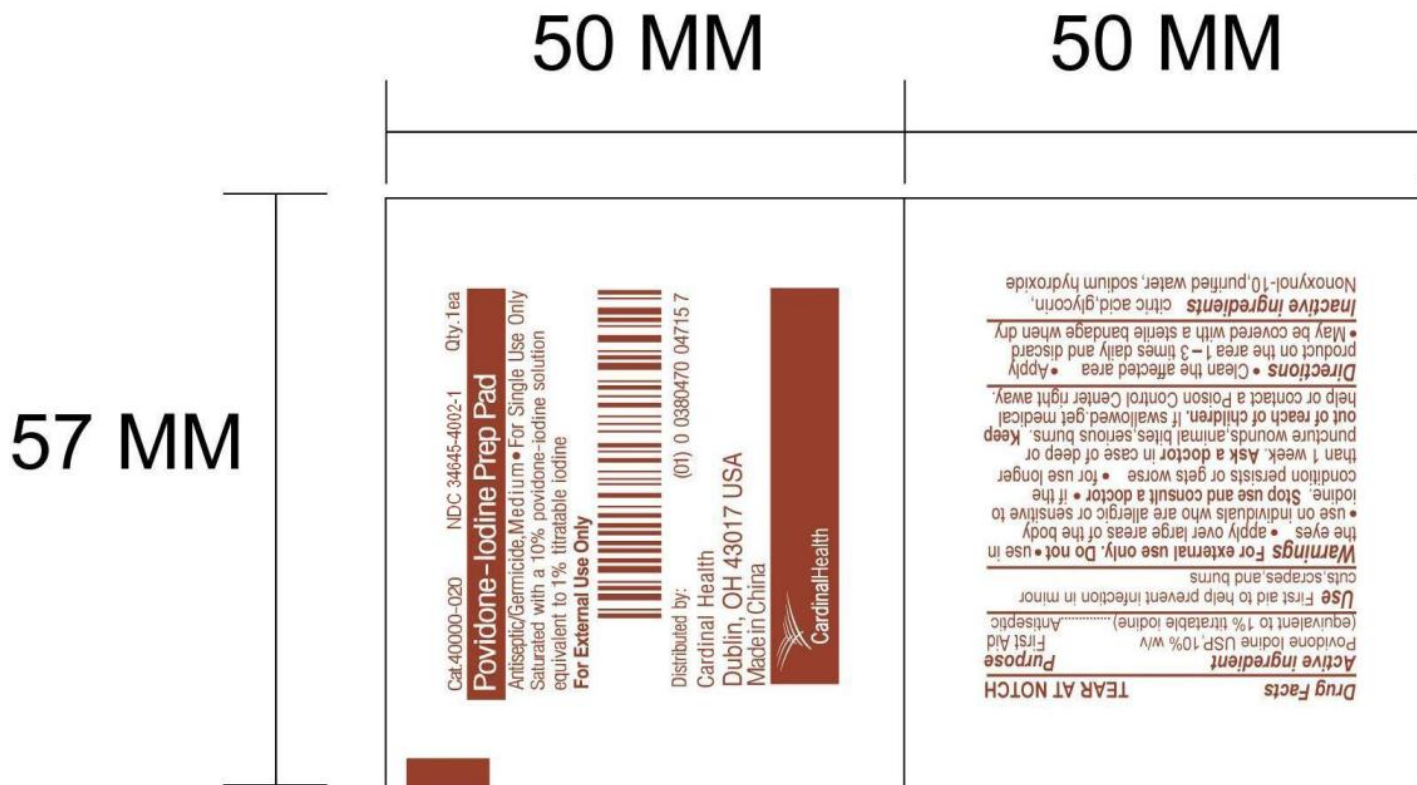
Apply product on the area 1-3 times daily and discard

May be covered with a sterile bandage when dry

Inactive ingredients

ctric acid, glycerin, Nonoxynol-10, purified water, sodium hydroxide

Image of Pouch Label



POVIDONE-IODINE PREP PAD

povidone-iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:34645-4002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	POVIDONE-IODINE	0.1 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:34645-4002-1	0.5 mL in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333	01/01/2008	

Labeler - Jiangsu Province JianErKang Medical Dressing Co.,Ltd. (530968767)

Registrant - Jiangsu Province JianErKang Medical Dressing Co., Ltd. (530968767)

Establishment

Name	Address	ID/FEI	Business Operations
Jiangsu Province JianErKang Medical Dressing Co., Ltd.		530968767	manufacture

Revised: 1/2010

Jiangsu Province JianErKang Medical Dressing Co.,Ltd.