

POVIDONE-IODINE PREP PAD - povidone-iodine swab
Wuxi Medical Instrument Factory

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

Item# 83791-817-030 NDC# 42947-611-10 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

Manufactured by:

Wuxi Medical Instrument Factory

No.86 East street, Zhangjing, Wuxi, Jiangsu 214194 China

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 a 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

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



POVIDONE-IODINE PREP PAD			
povidone-iodine swab			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42947-611
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:42947-611-10	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	01/01/2009	

Labeler - Wuxi Medical Instrument Factory (421292863)**Registrant** - Wuxi Medical Instrument Factory (421292863)**Establishment**

Name	Address	ID/FEI	Business Operations
Wuxi Medical Instrument Factory		421292863	manufacture

Revised: 3/2010

Wuxi Medical Instrument Factory