#### POVIDONE-IODINE - 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.

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# **Drug Facts**

# Item# 83791-817-001 NDC# 42947-621-01 Qty. 1ea

#### **Povidone-Iodine Swab Stick**

Antiseptic/Germicide \* For Single Use Only \* Avoid storing at excessive heat

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

Antiseptic

# Uses

Health-care antiseptic for preparation of the skin prior to surgery

First aid antiseptic to help prevent the risk of skin infection in minor cuts, scrapes, and burns.

# Warnings

# For external use only.

**Do not** \* use in the eyes \* use on individuals who are allergic or sensitive to iodine

\* apply over large areas of the body \* use as a first aid antiseptic longer than 1 week unless directed by a doctor.

# Discontinue use

If irritation and redness develop. If condition persists for more than 71 hours, consult a doctor.

# Consult a doctor in case of

\* deep or puncture wounds \* animal bites \* serious burns.

# 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

#### Stop use and consult a doctor

if the condition persists or gets worse.

# Keep out of reach of children.

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

#### Directions

# For preparation of the skin prior to surgery

- \* clean the affected area
- \* remove swab by stick
- \* apply to the operative site prior to surgery

# For use as a first aid antiseptic

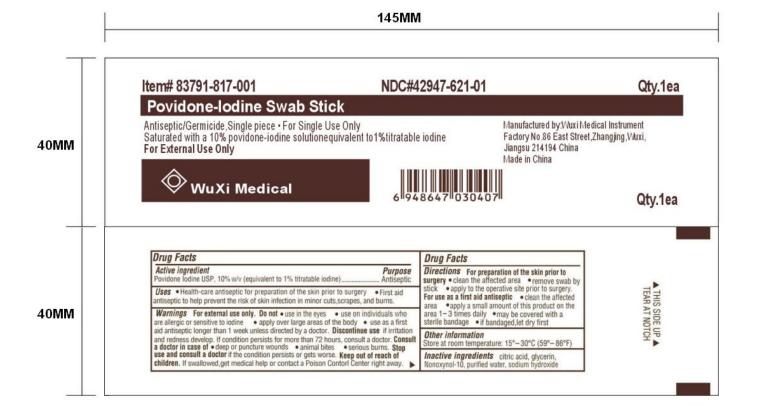
- \* clean the affected area
- \* apply a small amount of this product on the area 1-3 times daily
- \* may be covered with a sterile bandage
- \* if bandaged, let dry first

# Other information

Store at room temperature: 15° - 30° C (59°-86° F)

# **Inactive ingredients**

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



POVIDONE-IO	DINE									
povidone-iodine swab										
<b>Product Information</b>	on									
Product T ype		HUMAN OTC DRUG	Ite m C	Item Code (Source)			NDC:42947-621			
Route of Administration		TOPICAL								
Active Ingredient/Active Moiety										
Ingredient Name				Basis of Stren		gth	Strength			
PO VIDO NE-IO DINE (UNII: 85H0 HZU99 M) (IO DINE - UNII:9679 TC07X4)				PO VIDO NE-IO DINE			Е	0.1mL in $1mL$		
Packaging										
# Item Code	Pack	kage Description	Marketin	Aarketing Start D		Marke		eting End Date		
<b>1</b> NDC:42947-621-01	1.7 mL in	1 POUCH								
Marketing Information										
Marketing Category	Application Number or Monograph Citation			Marketing Start Date		Marketing End Date				
OTC monograph final	part333			0 1/0 1/2	0 1/0 1/20 0 8					

# Registrant - Wuxi Medical Instrument Factory (421292863)

Establishment										
Name	Address	ID/FEI	<b>Business Operations</b>							
Wuxi Medical Instrument Factory		421292863	manufacture							

Revised: 3/2010

Wuxi Medical Instrument Factory