

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.

Drug Facts

Item#83791-817-003 NDC#42947-631-03 Qty. 3ea

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

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

145MM

70MM

Item# 83791-817-003

NDC#42947-631-03

Qty.3ea

Povidone-Iodine Swab Stick

Antiseptic/Germicide, Three piece - 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



WuXi Medical



Qty.3ea

70MM

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TEAR AT NOTCH

POVIDONE-IODINE

povidone-iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42947-631
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0 HZU99M) (IODINE - UNII:9679 TC07X4)	POVIDONE-IODINE	0.1 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.0003 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42947-631-03	5.5 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 - 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