

POVIDONE-IODINE - 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.40000-050 NDC 34645-4001-4 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

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

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

Image of Pouch Label

145MM

70MM

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TEAR AT NOTCH

POVIDONE-IODINE

povidone-iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:34645-4001
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:34645-4001-4	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 - 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.