

JIANZE POVIDONE IODINE SCRUB - povidone-iodine liquid
Changzhou Jianze Sanitary Material 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.

JIANZE POVIDONE IODINE SCRUB SWABSTICK

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ACTIVE INGREDIENT

Povidone Iodine USP, 10% W/V (equivalent to 1% titratable iodine)

PURPOSE

Antiseptic

USE:

- 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 on the eyes
- use on individuals who are allergic or sensitive to iodine
- apply over large area 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

Consult a doctor in case of

- deep or puncture wounds
- animal bites
- serious burns

STOP USE AND CONSULT A DOCTOR

if the condition persists or gets worse.

KEEP OUT OF REACH OF CHILDREN.

In 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 degrees - 30 degrees C (59 degrees - 86 degrees F)

INACTIVE INGREDIENTS:

Citric Acid, Purified Water, Sodium Hydroxide, Nonoxynol-10, Glycerin

JIANZE POVIDONE IODINE SCRUB SWABSTICK 25 COUNT of 3 swabsticks (50666-006-01)



POVIDONE IODINE SCRUB SWABSTICK

REF 600-0410

10% Povidone Iodine, USP For Hospital and Professional Use Only

Manufactured by:
Changzhou Jianze Sanitary Material Co., Ltd.
Changzhou City, Jiangsu Province, China

3ea

Lot: JZ31512
Exp: 03/14

Drug Facts

Active ingredient

Povidone Iodine USP, 10% W/V (equivalent to 1% titratable iodine)

Purpose

Antiseptic

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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 banded, let dry first.

Other information

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

Inactive ingredients

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

160X90X150MM

490c

Qty. Box of 25x3 ea

For Hospital and Professional Use Only

10% Povidone Iodine, USP
POVIDONE IODINE SCRUB SWABSTICK

REF 600-0401



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povidone-iodine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50666-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (POVIDONE-IODINE - UNII:85H0HZU99M)	POVIDONE-IODINE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
NONOXYNOL-10 (UNII: K7O76887AP)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50666-006-01	25 in 1 BOX		
1		4.5 g in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333E	06/14/2012	

Labeler - Changzhou Jianze Sanitary Material Co., Ltd. (421279569)

Registrant - Changzhou Jianze Sanitary Material Co., Ltd. (421279569)

Establishment

Name	Address	ID/FEI	Business Operations
Changzhou Jianze Sanitary Material Co., Ltd.		421279569	manufacture

Revised: 6/2012

Changzhou Jianze Sanitary Material Co., Ltd.