

POVIDONE IODINE IMPREGNATED- povidone iodine sponge
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.

Impregnated Winged Sponges - Two Sponges Sticks Impregnated with 100ml Povidone Iodine (Scrub)

Active Ingredients

Povidone Iodine, USP 7.5% (0.75% available Iodine)

Purpose

Antiseptic

Uses

For preparation of skin and mucous membranes prior to surgery

Warnings

For external use only

Avoid use on persons allergic to iodine

Stop use and ask a doctor if

Skin shows symptoms of irritation, sensitivity, redness, pain or swelling

Keep out of reach of children

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

Directions

open pouch at tear notch

use sponge sticks to prep desired area

Other information

store at room temperature

avoid excessive heat (above 104 °F/40 °C)

protect from freezing

latex free

Inactive Ingredients

purified water, hydroxyethylcellulose, Nonylph

Package Label



Impregnated Sponges Sticks

Two Sponges Sticks Impregnated with
100 mL Povidone Iodine Topical Solution (Scrub)

Drug Facts	
Active ingredient	Purpose
Povidone Iodine, USP 7.5% (0.75% available iodine)	Antiseptic
Uses	
■ for preparation of skin and mucous membranes prior to surgery	
Warnings	
■ for external use only ■ avoid use on persons allergic to iodine	
Stop using this product and ask a doctor if	
■ skin shows symptoms of irritation, sensitivity, redness, pain or swelling	
Keep out of reach of children	
■ if swallowed, get medical help or contact a Poison Control Center right away	
Directions	
■ open pouch at tear notch ■ use sponge sticks to prep desired area	
Other information	
■ store at room temperature ■ avoid excessive heat (above 104°F/40°C)	
■ protect from freezing ■ latex free	
Inactive ingredients	
■ purified water, Hydroxyethylcellulose, Nonylph	

Foil resists ETO penetration. Meets proposed sterilant residue limit for pharmaceuticals and devices contacting skin.

Manufactured by:
Jiangsu Province JianErkang Medical Dressing Co.,Ltd
Zhixi Town Jintan City Jiangsu Province China
Made in China

POVIDONE IODINE IMPREGNATED

povidone iodine sponge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:34645-1032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	7.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
HYDROXYETHYL CELLULOSE (100 MPAS AT 2 %) (UNII: R33S7TK2EP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:34645-1032-1	10 in 1 BOX	03/03/2015	
1		100 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/03/2015	

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(34645-1032)

Revised: 12/2019

Jiangsu Province JianErKang Medical Dressing Co. ,Ltd.