

POVIDONE IODINE IMPREGNATED- povidone iodine sponge
Jianerkang Medical Co., Ltd

Drug Facts

Active Ingredients

Povidone Iodine, USP 10% (1.0% 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 104oF/40oC) protect from freezing latex free

Inactive Ingredients

hydroxyethylcellulose, nonoxynol - 10, purified water

Package Labeling

NDC:34645-4010-4

REF 600-4492



Impregnated Sponges Sticks

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

Drug Facts	
Active ingredient	Purpose
Povidone Iodine, USP 10% (1.0% 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	
■ hydroxyethylcellulose, nonoxynol - 10, purified water	

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,China
<http://www.chinajek.com>

16x27cm

POVIDONE IODINE IMPREGNATED

povidone iodine sponge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:34645-4010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
NONOXYNOL-10 (UNII: K7O76887AP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:34645-4010-4	100 mL in 1 POUCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	01/01/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	01/01/2010	

Labeler - Jianerkang Medical Co., Ltd (530968767)

Establishment

Name	Address	ID/FEI	Business Operations
Jianerkang Medical Co., Ltd		530968767	manufacture(34645-4010)

Revised: 10/2023

Jianerkang Medical Co., Ltd