

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

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**Impregnated Winged Sponges - Four Large Winged Sponges Impregnated with 100ml Povidone Iodine Cleansing Solution (Paint)**

**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



Four Winged Sponges Impregnated with  
100 mL Povidone Iodine Cleansing Solution (Paint)

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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:34645-1028
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%)</b> (UNII: R33S7TK2EP)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:34645-1028-1	10 in 1 BOX	09/10/2015	
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 Drug	505G(a)(3)	09/10/2015	

**Labeler** - Jianerkang Medical Co., Ltd (530968767)**Establishment**

Name	Address	ID/FEI	Business Operations
Jianerkang Medical Co., Ltd		530968767	manufacture(34645-1028)

Revised: 10/2023

Jianerkang Medical Co., Ltd