POVIDONE IODINE TOPICAL SOLUTION PAINT- povidone iodine 10% liquid 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.

Povidone Iodine Topical Solution Paint

Drug Facts

Active Ingredient

Povidone-Iodine, USP 10% (1.0% available iodine)

Purpose

patient preoperative prep

Use

prepping intact skin and mucous membranes prior to sugery

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

Patient preoperative prep

- apply solution to operative site following povidone iodine scrub application
- using a circular motion, start at incision site and move outward
- remove all soiled underdrapes
- do no allow solution to pool

Other information

- store at room temperature
- avoid excessive heat (above 104 degrees F/40 degrees C)
- protect from freezing
- latex free

Inactive Ingredients

Purified Water, nonylphenol ethoxylate, glycerol

Package Labeling

NDC:

REF 600-0599

Povidone Iodine Topical Solution, Paint

Antiseptic

With Moisturizers

Povidone-Iodine, USP 10% Topical Solution

For preparation of skin and mucous membranes prior to surgery.

Helps reduce bacteria that may cause skin infection.

Net Contents: 4 gallon(3.785 litre)

Manufactured by:

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



JianErKang Medical Dressing Co., Ltd.

Drug Facts

Active ingredient
Povidone-lodine, USP 10%

Purpose

patient (1.0% available iodine) preoperative prep

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Inactive ingredients

purified water, nonylphenol ethoxylate, glycerol

NDC: REF 600-0594

Povidone Iodine Topical Solution, Paint

Antiseptic

With Moisturizers

Povidone-Iodine, USP 10% Topical Solution

For preparation of skin and mucous membranes prior to surgery.

Helps reduce bacteria that may cause skin infection.

Net Contents: 2 fl. oz. (59 ml)

Manufactured by:

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



JianErKang Medical Dressing Co., Ltd.

Drug Facts

Active ingredient
Povidone-lodine, USP 10%

Purpose

Povidone-lodine, USP 10% patient (1.0% available iodine) preoperative prep

Uses

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Warnings

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Inactive ingredients

purified water, nonylphenol ethoxylate, glycerol

POVIDONE IODINE TOPICAL SOLUTION PAINT

povidone iodine 10% liquid

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:34645-1040

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
POVIDONE-IO DINE (UNII: 85H0 HZU99M) (IO DINE - UNII:9679TC07X4)
IO DINE
100 mg in 1 mL

Inactive Ingredients

Ingredient Name Strength
WATER (UNII: 059QF0KO0R)
NONOXYNOL-9 (UNII: 48Q180SH9T)
GLYCERIN (UNII: PDC6A3C0OX)

Packaging

#		Item Code	Item Code Package Description		Marketing End Date
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1 NDC:34645-1040-1 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product 03/31/2015 08/21/2018

2 NDC:34645-1040-2 59 i	nL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2015							
Marketing Information									
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date						
OTC monograph not final	part333A	03/31/2015							
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Labeler - Jiangsu Province Jianerkang Medical Dressing Co., Ltd. (530968767)

Establishment							
Name	Address	ID/FEI	Business Operations				
Jiangsu Province Jianerkang Medical Dressing Co., Ltd.		530968767	manufacture(34645-1040)				

Revised: 8/2018 Jiangsu Province Jianerkang Medical Dressing Co., Ltd.