

FULL CARE POVIDONE IODINE SOLUTION- povidone-iodine solution
Shaoxing Fuqing Health Products 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.

Active Ingredient: Povidone-Iodine USP 10% (1.0% Available Iodine)

Purpose: Antiseptic

Use: Prepping Intact Skin and Mucous Membranes Prior to Surgery

Warnings:

For external use only

Avoid use on persons allergic to iodine

Keep out of reach of children. If swallowed, get medical help or consult a poison control center right away

Stop use and ask a doctor if

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

Directions: Patient Preoperative Prep:

Use full strength. Apply solution to preoperative site following povidone iodine scrub application. Use a circular motion, start at incision site and move outward. Remove all soiled underdrapes. Do not allow solution to pool.

Other information

- Store at room temperature.
- Avoid excessive heat (above 104F/40C)
- Protect from freezing)
- Latex free

Inactive Ingredient

Citric Acid, Glycerin, Nonoxyl-10, Sodium Hydroxide, Water

NDC 65028-006-006

FULL CARE

POVIDONE-IODINE SOLUTION

Helps reduce bacteria that may cause skin infection.

Net Contents: 3 fl.oz (88.5ml)

LOT



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Drug Facts

Active Ingredient
 Povidone-iodine USP 10%
 (1.0% available iodine) **Purpose:** Antiseptic

Uses
 in Prepping intact skin and mucous membranes prior to surgery

Warnings
 in For external use only
 in Avoid use on persons allergic to iodine

Stop use and ask a doctor if:
 in Skin shows symptoms of irritation, sensitivity, redness, pain or swelling.

Keep out of reach of children.
 in If swallowed, get medical help or contact a Poison Control Center right away.

Directions: Patient preoperative prep
 in Use full strength in Apply solution to operative site following povidone iodine scrub application in Using a circular motion, start at incision site and move outward in Remove all occluded underdrapes in Do not allow solution to pool

Other information
 in Store at room temperature in Avoid excessive heat (above 104°F/40°C) in Protect from freezing in Latex free

Inactive Ingredients
 in Citric acid, glycerin, nonoxyl-10, purified water, sodium hydroxide.

FULL CARE POVIDONE IODINE SOLUTION

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65028-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONOXYNOL-10 (UNII: K7O76887AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65028-006-01	59 mL in 1 BOTTLE		
2	NDC:65028-006-02	88.5 mL in 1 BOTTLE		
3	NDC:65028-006-03	109 mL in 1 BOTTLE		
4	NDC:65028-006-04	50 mL in 1 BOTTLE		
5	NDC:65028-006-05	100 mL in 1 BOTTLE		
6	NDC:65028-006-06	150 mL in 1 BOTTLE		
7	NDC:65028-006-07	200 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	09/22/2014	

Labeler - Shaoxing Fuqing Health Products Co., Ltd. (530545003)

Registrant - Shaoxing Fuqing Health Products Co., Ltd. (530545003)

Establishment

Name	Address	ID/FEI	Business Operations
Shaoxing Fuqing Health Products Co., Ltd.		530545003	manufacture(65028-006)

Revised: 9/2014

Shaoxing Fuqing Health Products Co., Ltd.