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:

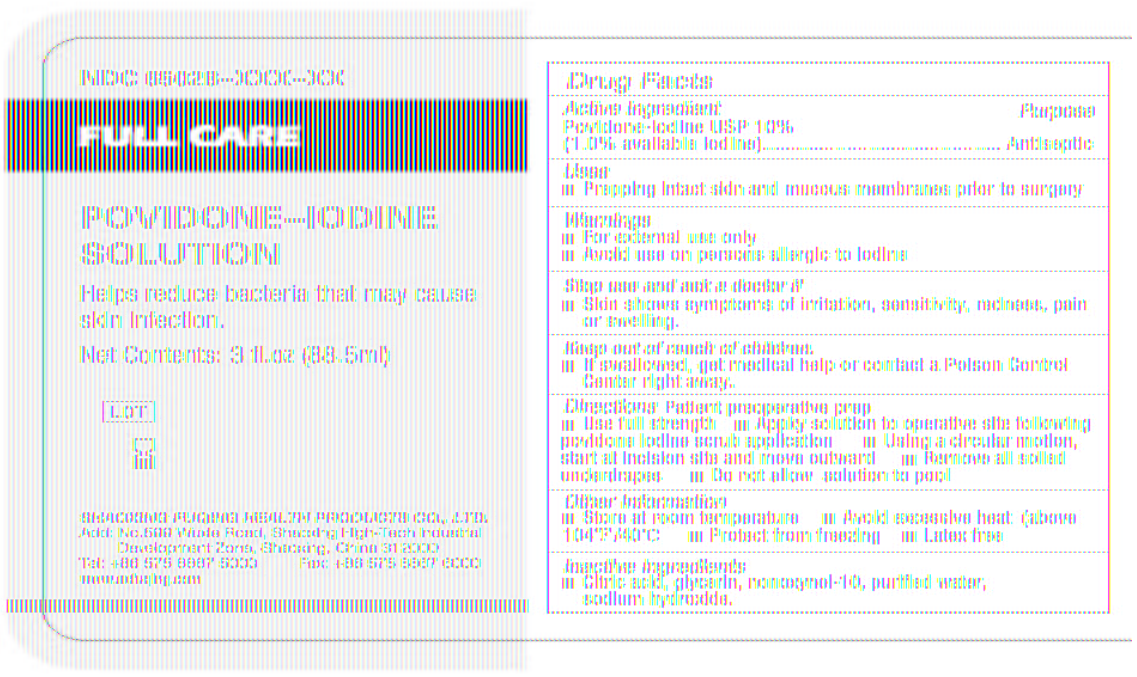
Use full strength. Apply solution to preoperative site following povidone iodine scrub application. Use a circular motion,start as incision site and move onward. Remove all soiled underdrapes. Do not allow solution to pool.

Other information

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

Inactive Ingredient

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



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: 059QF0KO0R)	
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.