

FULL CARE POVIDONE IODINE PREP PAD- 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%)

Purpose: Antiseptic

Use: Antiseptic skin preparation

Warnings:

Do not use

- if allergic to iodine
- in the eyes

For external use only

Keep out of reach of children.

Ask a doctor before use if injuries are

- deep or puncture wounds
- serious burns

Stop use and ask a doctor if

- redness, irritation, swelling, or pain persists or increases
- infection occurs

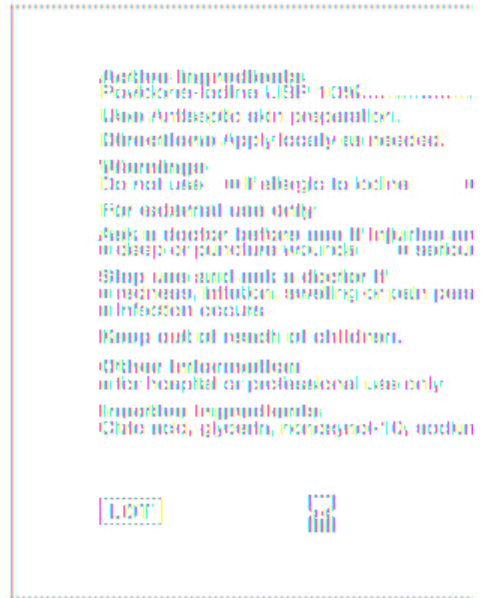
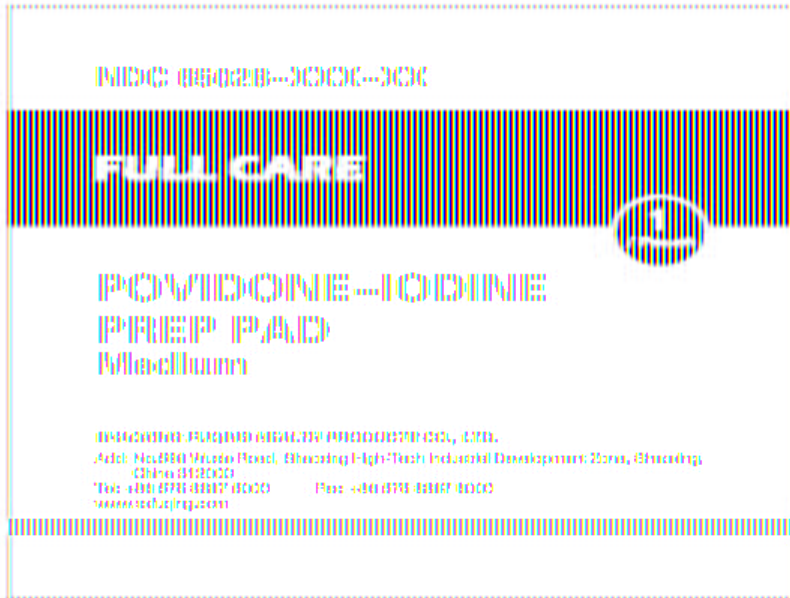
Apply locally as need

Other information

- For hospital or professional use only

Inactive Ingredient

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



FULL CARE POVIDONE IODINE PREP PAD
povidone-iodine solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65028-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	0.01 g in 1 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:65028-007-01	0.2 mL in 1 POUCH		
2	NDC:65028-007-02	0.4 mL in 1 POUCH		
3	NDC:65028-007-03	0.8 mL in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	10/17/2014	

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(65028-007)

Revised: 11/2014

Shaoxing Fuqing Health Products Co., Ltd.