## FULL CARE POVIDONE IODINE SWABSTICKS- povidone-iodine swab 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.

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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

Avoid "pooling" beneath patients.

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or consult a poison control center immediately

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, Nonoxyol-10, Sodium Hydroxide, Water





## FULL CARE POVIDONE IODINE SWABSTICKS

povidone-iodine swab

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65028-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
l	PO VIDO NE-IO DINE (UNII: 85H0 HZU99 M) (IO DINE - UNII:9679 TC07X4)	IODINE	0.2 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONOXYNOL-10 (UNII: K7O76887AP)	

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:65028-001-01	3 in 1 POUCH			
2	NDC:65028-001-02	1 in 1 POUCH			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	04/22/2014		

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

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

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Shaoxing Fuqing Health Products Co., Ltd.		530545003	manufacture(65028-001)	

Revised: 9/2014 Shaoxing Fuqing Health Products Co., Ltd.