

FULL CARE THREE 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.

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

NDC: 65028-001-01



◀ Tear Here Hold Upright Tear Here ▶

THREE POVIDONE-IODINE SWABSTICKS

Three 4-inch saturated swabsticks
STERILE UNLESS OPENED OR DAMAGED

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Drug Facts

Active Ingredients:

Povidone-iodine USP 10%

Use: Antiseptic skin preparation

Warnings:

Do not use if allergic to iodine

For external use only

Ask a doctor before use if injure
• deep or puncture wounds

Stop use and ask a doctor if
• redness, irritation, swelling
increase

• infection occurs

Acid pooling beneath patient

Keep out of reach of children.

In case of accidental ingestion
assistance or consult a toxicologist
immediately.

Directions: Apply locally as

Other information:

• for hospital or professional

Inactive Ingredients:

Citric acid, glycerin, monobyr,
hydrochloric acid, purified water

LOT



FULL CARE THREE POVIDONE IODINE SWABSTICKS

povidone-iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65028-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)		IODINE	0.2 g	
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:65028-005-01	3 in 1 POUCH		
2	NDC:65028-005-02	1 in 1 POUCH		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	09/12/2014		

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(65028-005)

Revised: 9/2014

Shaoxing Fuqing Health Products Co., Ltd.