

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

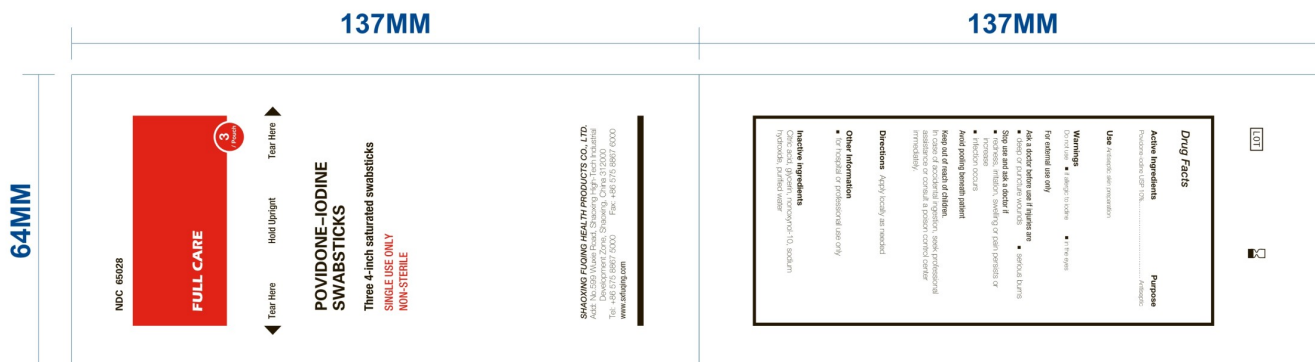
Apply locally as need

Other information

- For hospital or professional use only

Inactive Ingredient

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



Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65028-008
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:65028-008-01	3 in 1 POUCH; Type 0: Not a Combination Product	03/30/2018	
2	NDC:65028-008-02	1 in 1 POUCH; Type 0: Not a Combination Product	03/30/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/30/2018	

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(65028-008)