

POVIDONE-IODINE PAD - povidone-iodine swab
Shandong Haiyan Medical Manufacture 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.

Antiseptic Povidone-Iodine Prep Pad 10% Povidone-Iodine, 1% available Iodine. SHANDONG HAIYAN MEDICAL MANUFACTURE CO., LTD. www.haiyan-medical.com

Active Ingredient

Povidone Iodine 10% w/w (equivalent to iodine 1%)

Purpose

Antiseptic

Use

Antiseptic for preparation of the skin.

Warnings

For external use only.

Discontinue use if irritation and redness develop.

Keep out of reach of Children.

Directions

Apply locally as needed.

Other Information

Store at room temperature: 59°- 86°F(15 - 30°)

Inactive ingredients

Purified Water



Haiyan Medical

Antiseptic
**Povidone-Iodine
Prep Pad**

10% Povidone-Iodine, 1% Titratable Iodine

SHANDONG HAIYAN MEDICAL MANUFACTURE CO.,LTD

<http://www.haiyan-medical.com>

Drug Facts	
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Made in China

TEAR AT NOTCH

POVIDONE-IODINE PAD

povidone-iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42339-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (POVIDONE-IODINE - UNII:85H0HZU99M)	POVIDONE-IODINE	9.43 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42339-002-01	10 in 1 CONTAINER		
1		100 in 1 BOX		
1		0.6 g in 1 POUCH		
2	NDC:42339-002-02	100 in 1 CONTAINER		
2		100 in 1 BOX		
2		0.6 g in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	02/18/2012	

Labeler - Shandong Haiyan Medical Manufacture Co., Ltd. (421283439)

Establishment

Name	Address	ID/FEI	Business Operations
Shandong Haiyan Medical Manufacture Co., Ltd.		421283439	manufacture