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.

42339-003 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°C)

Inactive ingredients

Purified Water



Antiseptic

Povidone-lodine 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:42339-003

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	9.43 a in 100 a

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:42339-003- 01	10 in 1 CONTAINER	02/18/2012	
1		100 in 1 BOX		
1		0.6 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:42339-003- 02	100 in 1 CONTAINER	02/18/2012	
2		100 in 1 BOX		
2		0.6 g in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

- 101 110 111			
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

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Shandong Haiyan Medical Manufacture Co., Ltd.	421283439	manufacture(42339-003)

Revised: 8/2021 Shandong Haiyan Medical Manufacture Co., Ltd.