

POVIDONE-IODINE PREP PAD- povidone-iodine swab
Tongzhou Ruihong Medical Products Factory

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.

Drug Fact

Active Ingredient

POVIDONE-IODINE 10% W/v (equivalent to iodine 1%)

Purpose

Antiseptic

Warnings

For External use only.
Discontinue use if irritation and redness develop

Keep out of reach of children

Keep out of reach of children

Directions

Apply locally as needed.

Other information

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

Use

Antiseptic for preparation of the skin

Inactive Ingredients

Purified Water

STRICT[®]

NDC 58488-003-01

Antiseptic

Povidone-Iodine Prep Pad

10% Povidone-Iodine, 1% Titratable Iodine

Tongzhou Ruihong Medical Products Factory
No.28, Anxi Villege, Tongzhou District, Nantong, Jiangsu, China

Drug Facts	
Active Ingredient	Purpose
Povidone Iodine 10% w/v (equivalent tp iodine 1%)	Antiseptic
Use	
Antiseptic for preparation of the skin.	
Non-sterile Solution Applicator is sterile if package is intact	
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	

----- TEAR AT NOTCH -----

POVIDONE-IODINE PREP PAD

povidone-iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58488-003
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58488-003-01	1 in 1 PACKAGE; Type 0: Not a Combination Product	05/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	05/20/2013	

Labeler - Tongzhou Ruihong Medical Products Factory (421312726)

Establishment

Name	Address	ID/FEI	Business Operations
Tongzhou Ruihong Medical Products Factory		421312726	manufacture(58488-003)

Revised: 5/2016

Tongzhou Ruihong Medical Products Factory