

POVIDONE IODINE- povidone-iodine swab
Yinjing Medical Technology (Shanghai) 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.

POVIDONE-IODINE SWABSTICK

Drug Facts

Active Ingredients

Povidone-Iodine 10% w/w
(1% titratable iodine)

Purpose

Antiseptic

Use

First aid antiseptic to help prevent infection in scrapes, minor cuts and burns Antiseptic to prepare skin prior to surgery. Uses antiseptic skin preparation

Stop Use Section

Stop use and ask a doctor if skin irritation, redness, swelling, or pain occurs.

Warnings Section

Warnings • Do not use if allergic to iodine • For external use only • Do not use in eyes • Avoid pooling beneath patient • In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.

Keep Out of Reach of Children Section

Keep out of reach of children.

Directions Section

Directions apply locally as needed

Inactive Ingredients Section

Inactive ingredients Sodium hydroxide, water

Other Information Section

Other information
For Hospital or Professional Use Only.

Store at room temperature: 15°- 30 °

For professional and hospital use

Store at room temperature

LOT EXP.

IN IN

NDC:44019-236-01

POVIDONE-IODINE SWABSTICK

For External Use Only

1 swabstick/packet

Product Label

1只装

44mm



44mm



3只装

70mm

70mm

145mm



Drug Facts	
Active ingredient Povidone-iodine USP1.0%/w/w (equivalent to 1.0% tetrabromoiodine)	Purpose Antiseptic
Uses	
<ul style="list-style-type: none"> A broad spectrum antiseptic for topical application for preparation of the skin prior to surgery. First Aid antiseptic to help prevent the risk of skin infection in minor cut, scrapes and burns. 	
Warnings	
For external use only	
Do not use	
<ul style="list-style-type: none"> in the eyes, nose or mouth on individuals who are allergic or sensitive to iodine over large areas of the body as a first aid antiseptic longer than one week unless directed by a doctor 	
Discontinue use if irritation and redness develop. If condition persist for more than 72 hours or gets worse, consult a healthcare provider.	
Consult a healthcare provider in case of	
<ul style="list-style-type: none"> deep or puncture wounds animal bites serious burns if you are pregnant 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
For the preparation of the skin prior to surgery	
<ul style="list-style-type: none"> clean the treatment area remove applicator apply to the operative site prior to surgery allow to dry 	
For use as a first aid antiseptic	
<ul style="list-style-type: none"> clean the treatment area apply a small amount of this product on the treatment area 1-3 times daily as directed may be covered with a sterile bandage if bandaged, let dry before applying bandage to prevent possible irritation 	
Other information	
<ul style="list-style-type: none"> Store at room temperature Avoid excessive heat 	
Inactive ingredients	
Purified Water, Sodium Hydroxide	

POVIDONE IODINE

povidone-iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:440 19-236
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	

Packaging

Marketing Start Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44019-236-01	1 in 1 PACKET	08/03/2016	
1		1.6 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:44019-236-03	3 in 1 PACKET	08/03/2016	
2		5 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/03/2016	

Labeler - Yinjing Medical Technology (Shanghai) Co., Ltd. (530501535)

Registrant - Yinjing Medical Technology (Shanghai) Co., Ltd. (530501535)

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Yinjing Medical Technology (Shanghai) Co., Ltd.