POVIDONE IODINE- povidone-iodine swab
PSS World Medical, Inc.

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, USP Swabsticks

Active Ingredient

Povidone Iodine USP, 10% w/v

(equipvalent to 1% titratable iodine)

Purpose

Antiseptic

Uses

- Health-care antisptic for preparation of the skin prior to surgery
- First aid antiseptic to help prevent the risk of skin infection in minor cuts, scrapes, and burns

Warnings

For external use only.

Do not use

Do not use or apply

- in the eyes
- on individuals who are allergic or sensitive to iodine
- over large areas of the body
- as a first aid antiseptic longer than 1 week unless directed by a doctor

Stop use and consult a doctor

Discontinue use if irritation and redness develop.

Consult a doctor in case of

- deep or puncture wounds
- animal bites
- serious burns

Stop use and cosult a doctor if the condition persists or gets worse.

Keep out of reach of children

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If swallowed, get medical help or contact a Poison Control Center right away.

Directions

For preparation of the skin prior to surgery

Clean the affected area, remove swab by stick, apply to the operative site prior to surgery.

For use as a first aid antiseptic

Clean the affected area, apply a small amount of this product on the area 1-3 times daily. May be covered with a sterile bandage. If bandaged, let dry first.

Other information

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

Inactive Ingredients

Citrict Acid, Glycerin, Nonoxynol-8, Purified Water, Sodium Hydroxide

Questions

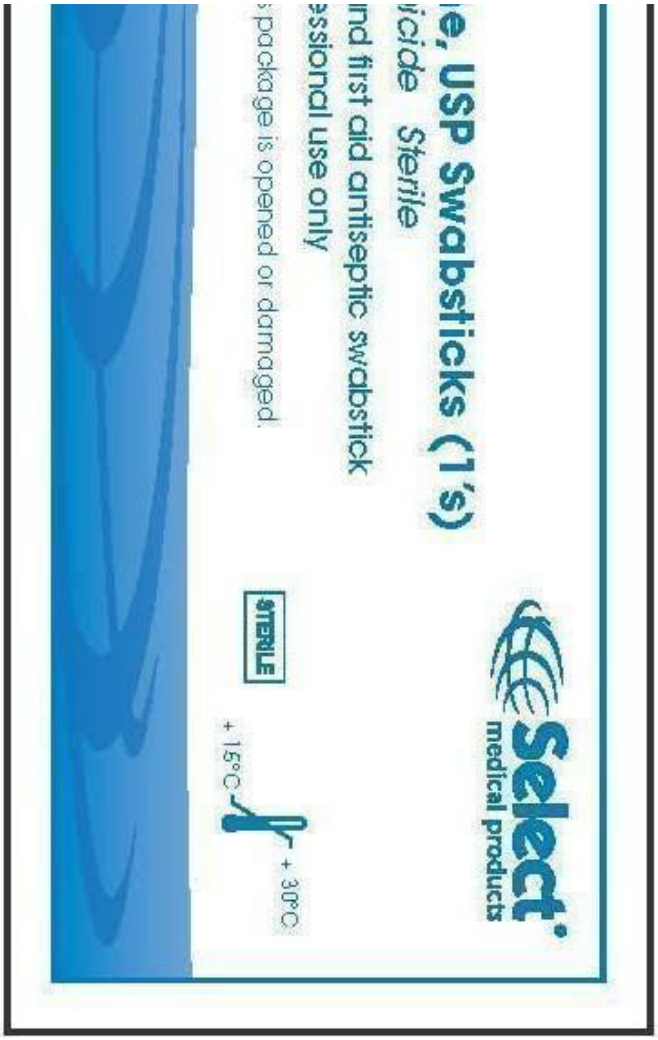
Questions about Select? 800-777-4908

Manufactured for PSS World Medical, Inc.

4345 Southpoint Blvd., Jacksonville, FL 32216

Made in China

Package Label



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986 Each

9986 Box

68345-863-01

1 each/pouch

50 pouches/box

68345-863-03

3 each/pouch

25 pouches/box

PPovidone Iodine, USP Swabsticks

AAntiseptic Germicide Sterile

- Topical pre-surgical and first aid antiseptic swabstick
- For hospital and professional use only

Single use only. Sterile unless package is opened or damaged.

POVIDONE IODINE

povidone-iodine swab

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:68345-863
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (IODINE)	POVIDONE-IODINE	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE	
GLYCERIN	
NONOXYNOL-8	
WATER	
SODIUM HYDROXIDE	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68345-863-01	2 mL in 1 POUCH		
2	NDC:68345-863-03	6 mL in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	09/05/2012	

Labeler - PSS World Medical, Inc. (101822682)

Registrant - PSS World Medical, Inc. (101822682)

Establishment

Name	Address	ID/FEI	Business Operations
Dalian Good Wood Medical Ltd.		529575699	manufacture(68345-863)

Revised: 10/2012 PSS World Medical, Inc.