MEDPRIDE SWABSTICKS- povidone iodine solution Shield Line LLC

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 Facts

Active Ingredient

Povidone Iodine 10% v/v (equivalent to 1% titratable iodine)

Purpose

Antiseptic

Uses

- health care antiseptic 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

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

Discontinue use

■ if irritation and redness develops

Consult a doctor in case of

- deep puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

■ if the condition persist or gets worse

Keep out of reach of children

If swallowed contact a doctor or Poison Control Center right away.

Directions

- for preparation of the skin prior to surgery, clean the affected area, remove the 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

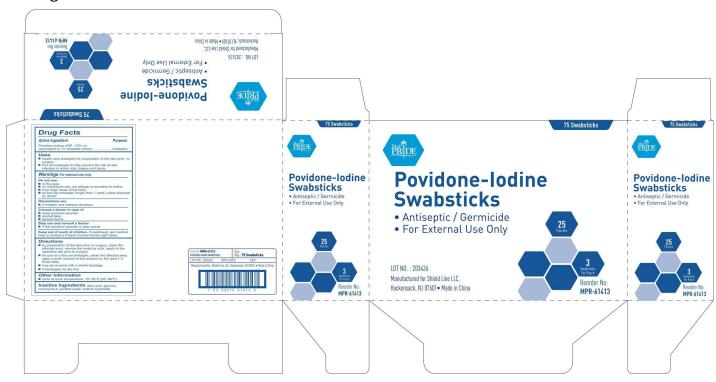
Other Information

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

Inactive Ingredients

citric acid, glycerin, nonoxynol-8, purified water, sodium hydroxide

Package Label



MEDPRIDE SWABSTICKS povidone iodine solution **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:52410-6141 **Route of Administration TOPICAL Active Ingredient/Active Moiety Basis of Strength Ingredient Name** Strength PO VIDO NE-IO DINE (UNII: 85H0 HZU99M) (IO DINE - UNII:9679TC07X4) **IODINE** 0.1 g

Inactive Ingredients				
Ingredient Name	Strength			
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)				
GLYCERIN (UNII: PDC6A3C0OX)				
NONOXYNOL-8 (UNII: OSD2GAP7HY)				
WATER (UNII: 059QF0KO0R)				
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)				

1	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:52410-6141-1	50 in 1 BOX; Type 0: Not a Combination Product	0 1/0 1/20 19			
2	NDC:52410-6141-3	75 in 1 BOX; Type 0: Not a Combination Product	0 1/0 1/20 19			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	05/01/2014				

Labeler - Shield Line LLC (078518916)

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