

**CERTUS PVP-1 PREP SWABSTICK - povidone-iodine swab**  
**Certus 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.*

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**Certus PVP-1 Prep Swabstick 210012 Drug Facts and Label**

**Drug Facts Box OTC Active Ingredient Section**

Povidone Iodine USP 10%

equivalent to 1% titratable iodine

**Drug Facts Box OTC Purpose Section**

Antiseptic

**Drug Facts Box OTC Indications & Usage Section**

health-care antiseptic for preparation of the skin prior to surgery

**Drug Facts Box OTC Warnings Section**

for external use only

**Drug Facts Box OTC Do Not Use Section**

in the eyes

over large areas of the body

on individuals who are allergic or sensitive to iodine

**Drug Facts Box OTC Ask Doctor Section**

in case of deep or puncture wounds, animal bites, or serious burns

**Drug Facts Box OTC Stop Use Section**

and consult a doctor if redness, irritation, swelling, or pain persists or increases

**Drug Facts Box OTC Keep Out of Reach of Children Section**

in case of accidental ingestion, seek professional assistance or consult a Poison Control Center immediately

**Drug Facts Box OTC Dosage & Administration Section**

for preparation of the skin prior to surgery

remove swab by stick

clean the area

apply product to the operative site prior to surgery

**Drug Facts Box OTC General Precautions Section**

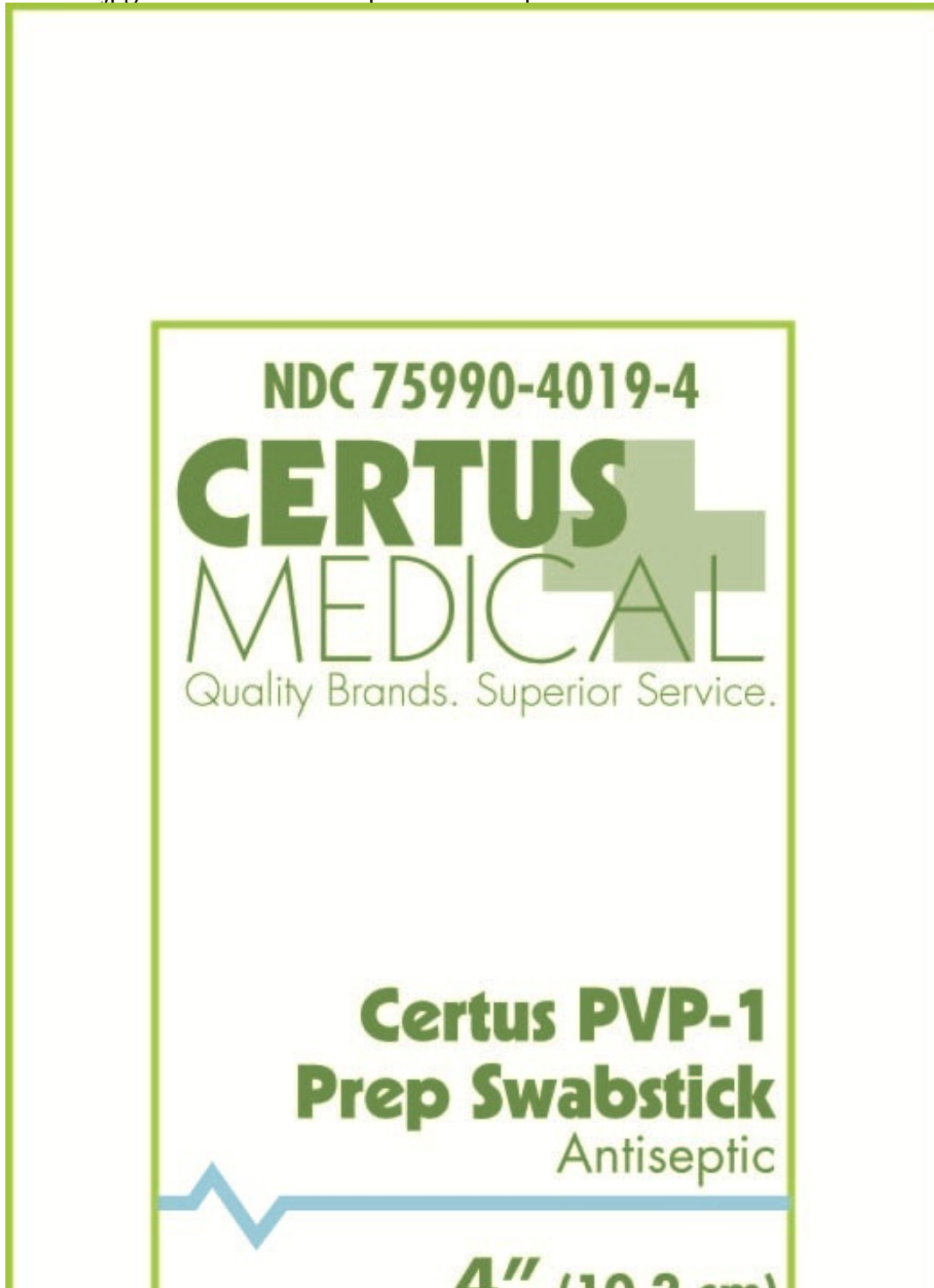
store at room temperature 15<sup>0</sup> - 30<sup>0</sup> C (59<sup>0</sup> - 86<sup>0</sup> F)

**Drug Facts Box OTC Inactive Ingredient Section**

disodium phosphate, glycerin, hydroxyethylcellulose, nonoxynol-10, dimethicone, water

**Certus PVP-1 Prep Swabstick 210012 pouch**

210012.jpg Certus PVP-1 Prep Swabstick pouch



(10.2 cm)  
Saturated Swabstick

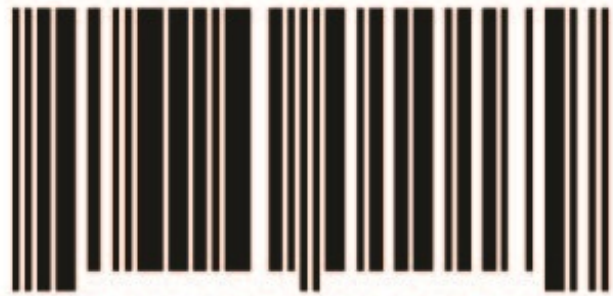


**Sterile**  
**Sterility guaranteed**  
**unless opened or**  
**damaged**

Manufactured in China for: Certus Medical, Inc.  
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210012

Lot#:  
Exp:



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## ***Drug Facts***

### ***Active Ingredient***

Povidone-Iodine USP 10%.....  
equivalent to 1% titratable iodine

### ***Purpose***

Antiseptic

***Use*** health-care antiseptic for preparation of the skin prior to surgery

### ***Warnings***

***For external use only***

**Do not use**  in the eyes  over large areas of the body  on individuals who are allergic or sensitive to iodine

**Ask a doctor** in case of deep or puncture wounds, animal bites, or serious burns

## ***Drug Facts (cont)***

**Stop use and consult a doctor** if redness, swelling, or irritation persists or increases

**Keep out of reach of children.** For professional assistance call 1-800-368-7773

***Directions*** for preparation:  for preoperative skin preparation  clean the area

### ***Other Information***

***Inactive Ingredients*** include: hydroxyethylcellulose, no



<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM PHOSPHATE, DIBASIC</b> (UNII: GR686LBA74)	
<b>NONOXYNOL-10</b> (UNII: K7O76887AP)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>HYDROXYETHYL CELLULOSE (2000 CPS AT 1%)</b> (UNII: S38J6RZN16)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75990-4019-4	2 mL in 1 POUCH		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/01/2011	

**Labeler** - Certus Medical, Inc. (966433653)

Revised: 4/2011

Certus Medical, Inc.