

**POVIDONE IODINE- povidone-iodine swab**  
**TwinMed 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.*

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**Triple Pack Povidone Iodine Swabsticks**

***Active Ingredient***

Povidone Iodine, 10% (equivalent 1% titratable Iodine)

***Purpose***

Antiseptic

***Uses:***

- First aid to help prevent infection in minor cuts, scrapes and burns
- Patient preoperative skin preparation.Helps to reduce bacteria that potentially can cause skin infection.

***Warnings:***

**For external use only.**

**Do not use:**

- In the eyes
- Longer than one week unless directed by a doctor
- On individuals who are allergic or sensitive to iodine
- Or apply over large areas of the body

**Ask a doctor before use if you have:**

- Deep or puncture wounds
- Animal bites
- Serious burns

**Stop use and ask a doctor if:**

- Irritation and redness develops
- If condition persists for more than 72 hours, consult a physician.

**Keep out of reach of children:**

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

***Directions:***

- Tear at notch
- Remove applicator
- Discard applicator after single use.

**As a first aid antiseptic**

- Clean affected area
- Apply 1 to 3 times daily.
- May be covered with a sterile bandage
- If bandaged, let dry first.

**For preoperative patient skin preparation:**

- Clean area
- Apply to operative site prior to surgery using applicator.

***Other Information:***

- Store at room temperature
- Avoid excessive heat

***Inactive Ingredients:***

Citric Acid, Glycerin, Polysorbate 80 (Tween 80), Sodium Citrate UPS, Sodium Phosphate Dibasic, Water

**Principal Display Panel**

PROCURE

HEALTHCARE PRODUCTS

Triple Pack

POVIDONE IODINE

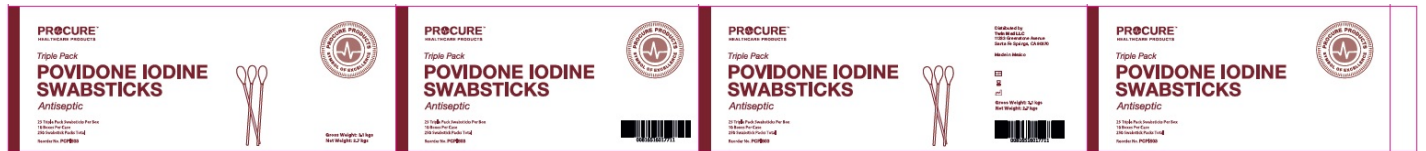
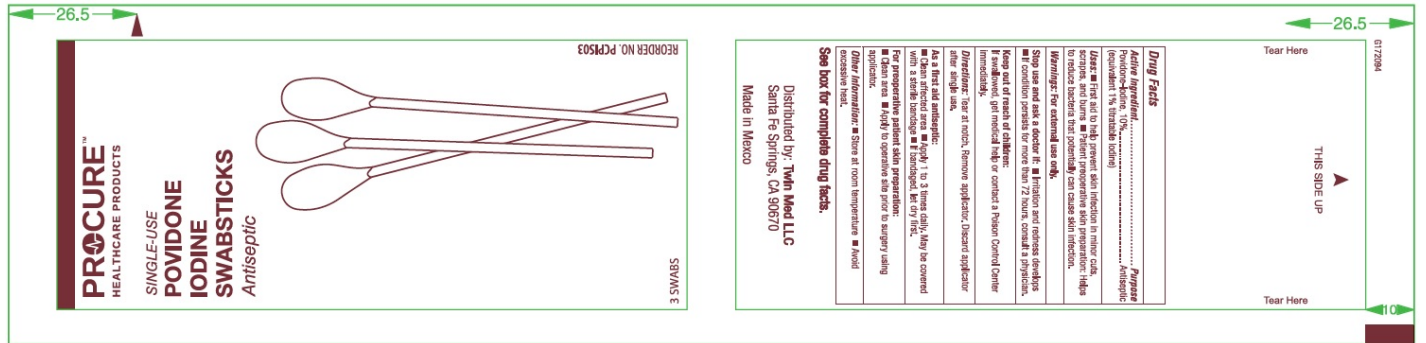
SWABSTICKS

Antiseptic

25 Swabsticks Per Box

10 Boxes Per Case

250 Swabstick Packs Total



<b>POVIDONE IODINE</b>			
povidone-iodine swab			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55681-753
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>

<b>POVIDONE-IODINE</b> (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)		IODINE	0.1 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
WATER (UNII: 059QF0KO0R)				
SODIUM PHOSPHATE DIBASIC DIHYDRATE (UNII: 94255I6E2T)				
GLYCERIN (UNII: PDC6A3C0OX)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55681-753-00	10 in 1 CASE	05/30/2023	
1		25 in 1 BOX		
1		1 in 1 PACKET; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/30/2023		

**Labeler** - TwinMed LLC (009579330)

**Registrant** - TwinMed LLC (009579330)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Sion Biotext Mexico SAPI de CV		951575186	manufacture(55681-753)

Revised: 5/2023

TwinMed LLC