

**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.*

-----

**Povidone Iodine Prep Pad**

***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

Single Pack

POVIDONE IODINE

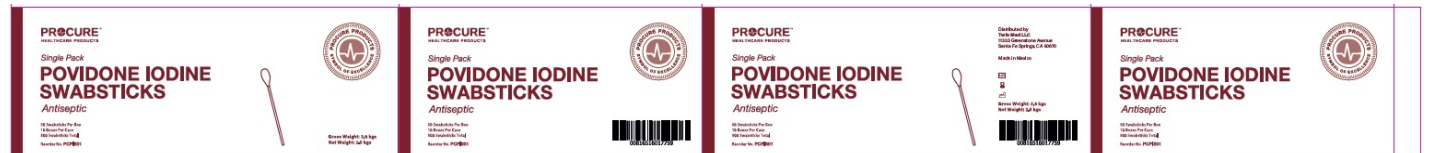
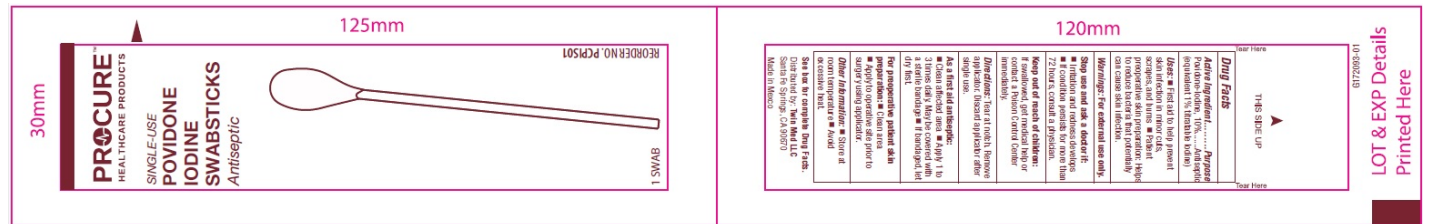
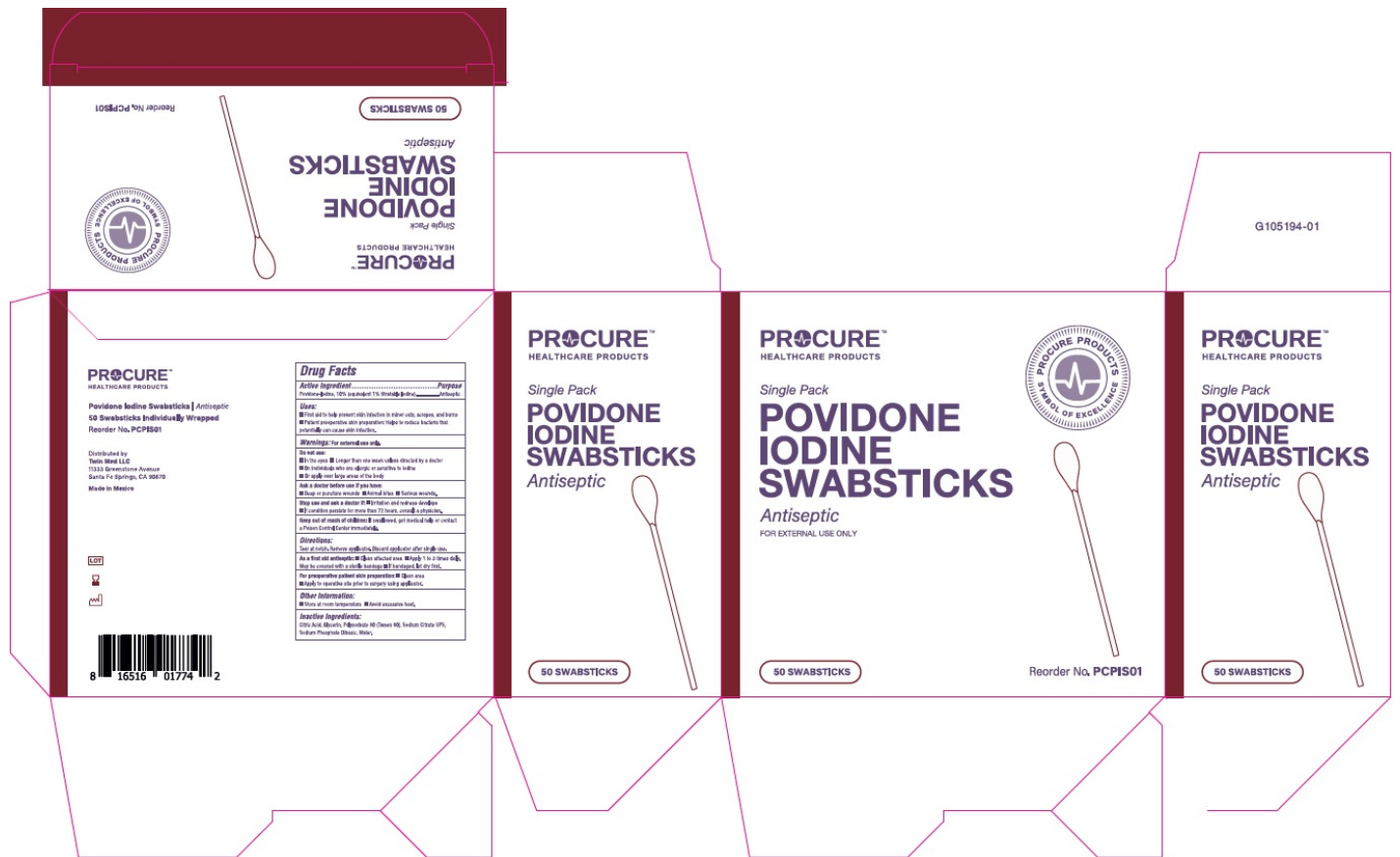
SWABSTICKS

Antiseptic

50 Swabsticks Per Box

10 Boxes Per Case

500 Swabsticks Total



POVIDONE IODINE			
povidone-iodine swab			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55681-752
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)		IODINE	0.1 g
Inactive Ingredients			

Ingredient Name	Strength
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM PHOSPHATE DIBASIC DIHYDRATE</b> (UNII: 9425516E2T)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55681-752-00	100 in 1 CASE	05/30/2023	
1		50 in 1 BOX		
1		1 in 1 PACKET; Type 0: Not a Combination Product		

### Marketing Information

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)

### Establishment

Name	Address	ID/FEI	Business Operations
Sion Biotext Mexico SAPI de CV		951575186	manufacture(55681-752)

Revised: 5/2023

TwinMed LLC