

**POVIDONE IODINE- povidone-iodine swab**  
**Sion Biotext Medical Ltd**

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**Povidone Iodine Prep Pad**

**Active Ingredient**

Povidone Iodine 10%

**Purpose**

Antiseptic

**Uses**

- Antiseptic cleanser to help prevent infection in minor cuts, scrapes and burns.
- For preparation of the skin prior to surgery.
- Helps reduce bacteria that can potentially cause skin infection.

**Warnings**

**For External Use Only.**

**Do not use**

- In the eyes
- As a first aid antiseptic for more than 1 week
- 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**

- Condition worsens or persists for more than 72 hours
- Irritation and redness develops

**Keep out of reach of children**

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

**Directions**

- Tear at notch

- Remove applicator
- Use only once

### As a first aid antiseptic

- Clean affected area
- apply 1-3 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

Nonoxynol-9, water

### Principal Display Panel

NDC 68786-130-01

50 Packets

Povidone-Iodine Swabsticks

Antisepetic/Germicide

For External Use Only

Sion Biotext Medical Ltd.



NDC #68786-130-01

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**POVIDONE IODINE**

povidone-iodine swab

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68786-130 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| <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           |

### Inactive Ingredients

| <b>Ingredient Name</b>                | <b>Strength</b> |
|---------------------------------------|-----------------|
| <b>NONOXYNOL-9</b> (UNII: 48Q180SH9T) |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)       |                 |

### Packaging

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                       | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|--|-----------------------------|---------------------------|
| 1        | NDC:68786-130-01 | 50 in 1 BOX                                      | 04/17/2013                  |                           |
| 1        |                  | 1 in 1 PACKET; Type 0: Not a Combination Product |                             |                           |
| 2        | NDC:68786-130-02 | 25 in 1 BOX                                      | 04/17/2013                  |                           |
| 2        |                  | 3 in 1 PACKET; Type 0: Not a Combination Product |                             |                           |
| 3        | NDC:68786-130-03 | 50 in 1 BOX                                      | 04/17/2013                  |                           |
| 3        |                  | 1 in 1 PACKET; Type 0: Not a Combination Product |                             |                           |
| 4        | NDC:68786-130-04 | 50 in 1 BOX                                      | 04/17/2013                  |                           |
| 4        |                  | 1 in 1 PACKET; Type 0: Not a Combination Product |                             |                           |
| 5        | NDC:68786-130-05 | 25 in 1 BOX                                      | 04/17/2013                  |                           |
| 5        |                  | 3 in 1 PACKET; Type 0: Not a Combination Product |                             |                           |
| 6        | NDC:68786-130-06 | 50 in 1 BOX                                      | 04/17/2013                  |                           |
| 6        |                  | 1 in 1 PACKET; Type 0: Not a Combination Product |                             |                           |

### Marketing Information

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC Monograph Drug        | M003  | 04/17/2013                  |                           |

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**Labeler** - Sion Biotext Medical Ltd (532775194)

**Registrant** - Sion Biotext Medical Ltd (532775194)

Revised: 1/2024

Sion Biotext Medical Ltd