

**LIGHTS POVINDONE IODINE SWABSTICK- povidone-iodine swab**  
**Lights Medical Manufacture Co., Ltd.**

*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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**61332-212**

Active Ingredient: Povidone-Iodine USP (10%)

Equivalent to 1% titratable Iodine

Purpose: Antiseptic

Use:

Health care antiseptic for preparation of skin prior to surgery.

First aid antiseptic to help prevent infection in minor cuts, scrapes and burns.

Warnings:

For external use only

Do not use or apply to the eyes \*to individuals who are allergic or sensitive to iodine, \*over large area of the body, \*as first aid antiseptic longer than a week unless directed by a doctor

Keep out of reach of children. If swallowed, get medical help or consult a poison control center right away

Discontinue use if irritation and redness develop. Consult a doctor in case of deep or puncture wounds, animal bites, or serious burns

Stop use and ask a doctor if infection occurs or if condition persists or increases

For preparation of the skin prior surgery: clean the affected area, remove swabstick, apply to the operative site prior to surgery

For use as first aid antiseptic: clean the affected area, apply a small amount of the product to the area 1-3 times daily. Maybe covered with a sterile bandage. If bandaged, let dry first.

Other information

- Store at room temperature

Inactive Ingredient

Citric acid, disodium phosphate, purified water

|  |                  |
|--|------------------|
|  | Povidone Iodine, |
|--|------------------|



LOT

◀ TEAR AT NOTCH ▶

LIGHTS®

NDC:

Povidone Iodine,  
USP Swabsticks (1's)  
Antiseptic Germicide  
Non-Sterile

• Topical and for external use only



1 each/pouch  
Reorder #GW1313S

USP Swabsticks (1's)

◀ TEAR AT NOTCH ▶

### Drug Facts

#### Active ingredient Purpose

Povidone Iodine USP, 10% w/v  
(equivalent to 1% titratable Iodine) .....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 or apply in the eyes • on individuals who are allergic or sensitive to iodine • over large areas of the body • as a first aid antiseptic longer than 1 week unless directed by a doctor.

**Discontinue use** if irritation and redness develop.

**Consult a doctor in case of** deep or puncture wounds • animal bites • serious burns.

**Stop use and consult a doctor** if the condition persists or gets worse.

**Keep out of reach of children.**

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

#### Directions

**For preparation of the skin prior to surgery** clean the affected area, remove 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. May be covered with a sterile bandage. If bandaged, let dry first.

#### Other information

Store at room temperature

#### Inactive ingredients

citric acid, disodium phosphate, purified water

LIGHTS MEDICAL MANUFACTURE CO.,LTD.  
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Area, Tianjin, China, 301700

## LIGHTS POVINDONE IODINE SWABSTICK

povidone-iodine swab

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:61333-212 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength     |
|--|-------------------|--------------|
| <b>POVIDONE-IODINE</b> (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4) | IODINE            | 1 g in 100 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)                              |          |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)            |          |
| <b>SODIUM PHOSPHATE DIBASIC DIHYDRATE</b> (UNII: 9425516E2T) |          |

### Packaging

| # | Item Code        | Package Description                                      | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:61333-212-01 | 1 in 1 POUCH   | 04/03/2023           |                    |
| 1 |                  | 1.5 g in 1 APPLICATOR; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333C                                 | 04/03/2023           |                    |

**Labeler** - Lights Medical Manufacture Co., Ltd. (529128649)

**Registrant** - Lights Medical Manufacture Co., Ltd. (529128649)

**Establishment**

| Name                                 | Address | ID/FEI    | Business Operations    |
|--------------------------------------|---------|-----------|------------------------|
| Lights Medical Manufacture Co., Ltd. |         | 529128649 | manufacture(61333-212) |

Revised: 4/2023

Lights Medical Manufacture Co., Ltd.