

### **3-STEP FIRST AID KIT- povidone-iodine, lidocaine hydrochloride, benzalkonium chloride Swabplus 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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### **3 Step First Aid Kit Medication Filled Swabs**

#### **Drug Facts**

#### **Active Ingredients**

#### **Antiseptic Swabs**

Lidocaine Hydrochloride 1.0%

Benzalkonium Chloride 0.11%

#### **Povidone Iodine swabs:**

Povidone Iodine 10%, equal to available Iodine 1% for antiseptic

#### **Purpose**

Lidocaine Hydrochloride for Pain Relief

Benzalkonium Chloride for Antiseptic

Povidone Iodine for Antiseptis

#### **Uses**

First aid to help prevent infection, and temporarily reliever pain and itching associated with minor cuts, scrapes and burn

#### **Keep out of reach of children**

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#### **Directions**

- Do not use if label seal is broken prior to purchase.
- Hold the swab vertically, with the color ring band tip upwards. Hold in the center of the stem with one hand and at the color band with the other.
- Bend the tip at the color band to one side until it snaps.
- Apply the product to the affected area.
- Discard swab after use.

#### **Warnings**

**For external use only.** Keep out of eyes. Non-Sterile. Discontinue use if irritation occurs. Do not insert in ear canal. Keep at room temperture. Avoid direct sunlight.

**Do not use.** Swabs if you are sensitive to any product ingredients. in the eyes. longer than one week unless directed by a doctor.

**Stop use and ask a doctor if** you have deep or puncture wounds, or serious burns. redness, irritation, sweeling or pain continues or increases, infection occurs

**Other information**

**For adult and children 2 and older:** Clean affected area. Apply 1 to 3 times daily. May be covered with a bandage.

**Children under 2 years of age:** Consult a doctor.

Avoid storing at excessive heat.

**Inactive Ingredients**

**Antiseptic swab:** Dizolidinyl Urea, Methylparaben, Propylparaben, Water

**Providone Iodine Swab:** Glycerin, Water

**Manufacturer Statement**

Soft cotton tip swabs individually filled with Antiseptic or Iodine. Ready to use and convenient to carry for fast, clean, safe first aid.

Patented and manufactured by Swabplus Inc. Rancho Cucamonga, CA 91730 USA

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**Package and label**

Image of first aid carton label

**Swabplus® 3-Step First Aid Kit**

Drug Facts	
<b>Antiseptic Swabs</b>	<b>Povidone Iodine Swabs</b>
<b>Active Ingredients</b> Lidocaine Hydrochloride 1.0% Benzalkonium Chloride 0.11%	<b>Purpose</b> Pain Relief Antiseptic
<b>Inactive Ingredients</b> Diazolidinyl Urea, Methylparaben, Propylparaben, Water (Aqua).	<b>Active Ingredient</b> Povidone Iodine 10% Equal to 1% available Iodine.
<b>Uses</b> First aid to help prevent infection, and temporarily relieve pain and itching associated with minor cuts, scrapes and burns.	<b>Inactive Ingredients</b> Glycerin, Potassium Sorbate, Sodium Benzoate, Sodium Hydroxide, Water (Aqua).
<b>Warnings</b> For external use only. Keep out of eyes. Non-Sterile. Discontinue use if irritation occurs. Do not insert in ear canal. Keep at room temperature. Avoid direct sunlight. <b>Do not use</b> • Swabs if you are sensitive to any product ingredients • in the eyes • longer than one week unless directed by a doctor <b>Stop use and ask a doctor if</b> • you have deep or puncture wounds, or serious burns • redness, irritation, swelling or pain continues or increases • infection occurs	<b>Uses</b> First aid to help prevent infection due to minor cuts, scrapes and burns.
<b>Keep out of reach of children</b>	
<b>Directions</b> Do not use if label seal is broken prior to purchase. • Hold the swab vertically, with the color band tip upwards. Hold in the center of the stem with one hand and at the color band with the other. • Bend the tip at the color band to one side until it snaps. • Apply the product to the affected area. • Discard swab after use. For adults and children 2 and older: Clean affected area. Apply 1 to 3 times daily. May be covered with a bandage. Children under 2 years of age: Consult a doctor.	
<b>Other information</b> Avoid storing at excessive heat.	



**3-STEP FIRST AID KIT**

povidone-iodine, lidocaine hydrochloride, benzalkonium chloride kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65734-000
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65734-000-23	1 in 1 CARTON		

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	2 mL
Part 2	1 PACKET	2 mL

## Part 1 of 2

### ANTISEPTIC AND ANESTHETIC SWAB

lidocaine hydrochloride, benzalkonium chloride liquid

#### Product Information

**Item Code (Source)** NDC:65734-125

**Route of Administration** TOPICAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	100 mg in 10 mL
<b>Benzalkonium Chloride</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	Benzalkonium Chloride	11 mg in 10 mL

#### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Diazolidinyl Urea</b> (UNII: H5RIZ3MPW4)	
<b>Methylparaben</b> (UNII: A2I8C7HI9T)	
<b>Propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65734-125-01	2 mL in 1 PACKET		

#### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	03/01/2003	

## Part 2 of 2

### POVIDONE-IODINE SWAB

povidone-iodine liquid

#### Product Information

<b>Item Code (Source)</b>	NDC:65734-119
<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	100 mg in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Water</b> (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65734-119-01	2 mL in 1 PACKET		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/01/2003	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/01/2003	

**Labeler** - Swabplus Inc. (876441549)

**Registrant** - Swabplus Inc. (876441549)

### Establishment

Name	Address	ID/FEI	Business Operations
Swabplus Inc.		876441549	repack(65734-000) , manufacture(65734-125, 65734-119)