

**INSECT BITE RELIEF- benzocaine solution**  
**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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**Insect Bite Relief Swabs**

**Drug Fact**

**Active ingredient**

Benzocaine 15%

**Purpose**

Benzocaine for Pain Relief

**Uses**

temporary relief of pain and itching associated with insect bites, scrapes, minor cuts, minor burns, sunburn, or skin irritation

**Warnings**

**For external use only.** do not bandage.

**Do not use.** in the eyes or apply over large areas of the body, particularly over raw surfaces or blistered area - if product gets into the eyes. flush thoroughly with water and obtain medical attention. longer than one week unless directed by doctor.

**Stop use and ask a doctor if.** condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days.

**Keep out of reach of children**

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

**Directions**

- ◆ Do not use if label seal is broken prior to purchase. Keep swabs in original container when not in use.
- ◆ 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.

**Administration**

**For adult and children 2 and older.** Apply directly onto affected area no more than 3 to 4 times daily.

**Children under 2 years of age.** Do not use, consult a doctor.

## Other information

Avoid storing at excessive heat.

## Inactive ingredients

Aloe Vera Gel, Ethoxydiglycol (diethylene glycol monoethyl ether), Glycerin, Menthol, PEG-8 (Polyethylene glycol 400), Propylene Glycol, Triclosan

## Package Display Panel

Image of insect bite carton label



### Swabplus® Insect Bite Relief Swabs

Relief from itching and pain due to mosquito and other insect bites, plus scrapes, minor burns, cuts, blisters and other skin irritation.

#### Drug Facts

Active ingredient	Purpose
Benzocaine 15%	Pain Reliever

**Uses** temporary relief of pain and itching associated with insect bites, scrapes, minor cuts, minor burns, sunburn, or skin irritation

#### Warnings

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**Other information** Avoid storing at excessive heat.

**Inactive ingredients** Aloe Vera Gel, Diazolidimyl Urea, Ethoxydiglycol, Glycerin, Menthol, Methylparaben, PEG-8, Propylene Glycol, Propylparaben, Triclosan

## INSECT BITE RELIEF

benzocaine solution

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:65734-300
Route of Administration	TOPICAL	DEA Schedule	

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (Benzocaine)	Benzocaine	150 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
Polyethylene Glycol 400	
DIETHYLENE GLYCOL MONOETHYL ETHER	
Glycerin	
PROPYLENE GLYCOL	
ALOE VERA LEAF	
Triclosan	
Menthol	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65734-300-36	36 in 1 PACKAGE		
1	NDC:65734-300-00	0.15 mL in 1 APPLICATOR		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/01/2003	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Swabplus Inc.		876441549	manufacture(65734-300), relabel(65734-300), repack(65734-300)