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.

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 throughly 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



INSECT BITE RELIEF

benzocaine solution

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

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	150 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
Polyethylene Glycol 400 (UNII: B697894SGQ)		
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8 X02B)		
Glycerin (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
Triclosan (UNII: 4NM5039Y5X)		
Menthol (UNII: L7T10EIP3A)		

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 Info	rmation		
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)

Revised: 4/2013 Swabplus Inc.