BENZOCAINE - benzocaine swab Dynarex Corporation

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.

Benzocaine Sting & Bite Pad

Active Ingredient

<u>Active Ingredient</u> <u>Purpose</u>

Benzocaine, 6% w/v Topical Analgesic

Isopropyl Alcohol, 70% w/v Antiseptic

Purpose

• For temporary relief of pain and itching associated with minor burns, scrapes and insect bites.

Keep Out of Reach of Children

- Keep out of reach of children.
- If swallowed, get medical help or contact a Poison Control Center.

Indications and Usage

• For temporary relief of pain and itching associated with minor burns, scrapes and insect bites.

Warnings

Warnings:

- For external use only.
- Flammable, keep away from fire or flame.

Dosage

Directions:

- Adults and children 2 years of age and older, apply to affected area 3-4 times daily.
- Children under 2 years; consult a physician.

Inactive Ingredients

• Inactive Ingredient: Water.

Do Not Use

Do not use:

- With electrocautery procedures.
- In the eyes.

Stop Use

Stop use:

- If irritation and redness develop.
- If condition persists for more than 72 hours, consult a physician.

Storage and Handling

- Avoid excessive heat.
- Store at room temperature: 15 30 degrees C (59 86 degrees F)

Principal Display

Sting and Bite Pad



DO NOT USE: With electrocautery procedures. In the eyes. STOP USE: If irritation and redness develop. If condition persists for more than 72 hours, consult a physician. CAUTION: Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. **DIRECTIONS:** For adults and children 2 years of age and older, apply to affected area 3-4 times daily. For children under 2 years of age, consult a physician before use. **OTHER INFORMATION:** Store at room temperature 15°-30°C (59°-86°F). Avoid excessive heat.

Dynarex Corporation Orangeburg, NY 10962

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BENZOCAINE

benzocaine swab

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-235	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5)	BENZOCAINE	0.12 mL		

Inactive Ingredients		
Ingredient Name	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
WATER (UNII: 059QF0KO0R)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-235-01	3000 in 1 CASE		
1		1 in 1 PACKET		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part348	0 1/24/20 11		

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Establishment			
Name	Address	ID/FEI	Business Operations
Taizhou Kanglin Health Protection Products Co Ltd		530576131	manufacture

Revised: 3/2011 Dynarex Corporation