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 and Bite

Active Ingredient

Active Ingredient	Purpose
Benzocaine, 6% w/v	Topical Analgesic

Purpose for Benzocaine

- For temporary relief of pain and itching associated with minor burns, sunburn, scrapes and insect bites or minor skin irritations

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, sunburn, scrapes and insect bites or minor skin irritations.

Warnings

Warnings: Benzocaine

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

Dosage

Directions:

- For adults and children 2 years of age and older, apply to affected area not more than 3-4 times daily.
- Children under 2 years; consult a physician.

Inactive Ingredients

- Inactive Ingredients: Isopropyl Alcohol, Water.

DO Not Use

Do not use:

With electrocautery procedures.

Stop Use

Stop use:

If irritation and redness develop.
If condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use and consult a doctor.

Storage and Handling

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

Principal Display Panel

Dynarex Sting and Bite

Benzocaine.jpg

BENZOCAINE

benzocaine swab

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-246
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	60 mg in 1 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:67777-246-01	2 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	07/20/2011	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Establishment

Name	Address	ID/FEI	Business Operations
Phoenix Innovative Healthcare Manufacturers Private Limited		650687176	manufacture(67777-246)

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