

FIRST AID ONLY STING RELIEF PAD- benzocaine patch

Acme United 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.

First Aid Only Sting Relief Pad

Active Ingredients

Active Ingredients Benzocaine, 6%

Purpose

Topical Analgesic

Use

Use For temporary relief of pain and itching associated with minor burns, scapes and insect bites

Warnings

Warnings •for external use only •flammable, keep away from fire or flame

Do Not Use

Do Not Use •in the eyes •if contact occurs, flush eyes with water

Keep out of reach of children

Keep out of reach of children if swallowed get medical help or contact a Poison Control Center right away

Directions

Directions •apply to affected area not more than 3 to 4 times daily, for adults and children 2 years of age or older

•Children under 2 years: consult physician

Other Information

Other Information Store at room temperature 15° - 30°C (59° - 86°F)

Inactive Ingredients

Inactive Ingredients isopropyl alcohol, purified water

Package Principal Display Panel

Component# M327
Description Sting Relief Pad, Wrapper Art (Planet)
Version revA
Date 05.31.17
Specs See Dieline / 1C (Pantone 166)

Drug Facts by Planet



FIRST AID ONLY STING RELIEF PAD

benzocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-5201(NDC:44019-520)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	6 g in 100 g

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:0924-5201-01	1 in 1 POUCH	07/31/2017	
1		0.42 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/31/2017	

Labeler - Acme United Corporation (001180207)**Establishment**

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-5201) , repack(0924-5201)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-5201) , repack(0924-5201)