FIRST AID AND BURN- benzalkonium chloride, lidocaine hydrochloride cream 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.

Drug Facts

Active ingredients

Benzalkonium Chloride 0.13%

Lidocaine HCl 0.5%

Purpose

First Aid Antiseptic

Topical analgesic

Uses

- for the temporary relief of pain associated with minor burns
- helps protect against harmful bacteria

Warnings

For external use only

Keep out of reach of children.

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

Do not use

- in eyes
- in large quantities
- over raw or blistered areas, or on deep puncture wounds, animal bites, serious burns
- for more than one week unless directed by a doctor

Stop use and ask a doctor if

• the condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days

Directions

Adults and children 2 years and over: clean affected area, apply small amount not more than 3 to 4 times daily

Children under 2 years: do not use, consult a doctor

Other information

- store at room temperature (do not freeze)
- do not use any opened or torn packets

Inactive ingredients

aloe vera, emulsifying wax, ethyl alcohol, methylparaben, mineral oil, paraffin, propylparaben, purified water, white petrolatum, white wax

Questions?

1-800-275-3433

PRINCIPAL DISPLAY PANEL - Pac-Kit 12 count box

PAC-KIT FIRST AID

First Aid Burn Cream Packets

Paquetes de crema para quemaduras

12 First Aid Burn Cream Packets, 0.9gm ea.

12 paquetes, 0,9 gm cada uno.

Reorder #13-006

ANSI Z308. 1-2009

First Aid Burn Cream

Crema para Quemaduras

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First Aid **Burn Cream Packets**

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Reorder #13-006

ANSI Z308, 1-2009

UNAQUEOUSED AREA





Drug Facts

Active ingredients
Benzalkonium Chloride 0.139

Purpose First Aid Antiseptic

Topical Analgesic

Burn Cream



FIRST AID AND BURN

benzalkonium chloride, lidocaine hydrochloride cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-5701	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
benzalkonium chloride (UNII: F5UM2KM3W7) (benzalkonium - UNII:7N6JUD5X6Y)	benzalkonium chloride	1.3 mg in 1 g		
lidocaine hydrochloride (UNII: V13007Z41A) (lidocaine - UNII:98PI200987)	lidocaine hydrochloride	5 mg in 1 g		

Inactive Ingredients	
Ingredient Name	Strength
aloe vera leaf (UNII: ZY8 1Z8 3H0 X)	
alcohol (UNII: 3K9958V90M)	
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: 1900E3H2ZE)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
petrolatum (UNII: 4T6H12BN9U)	
white wax (UNII: 7G1J5DA97F)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-5701-05	12 in 1 BOX		
1	NDC:0924-5701-01	0.9 g in 1 PACKET		
2	NDC:0924-5701-06	25 in 1 BOX		
2	NDC:0924-5701-01	0.9 g in 1 PACKET		
3	NDC:0924-5701-07	60 in 1 BOX		
3	NDC:0924-5701-01	0.9 g in 1 PACKET		
4	NDC:0924-5701-08	144 in 1 BOX		
4	NDC:0924-5701-01	0.9 g in 1 PACKET		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	0 1/27/20 12		

Labeler - Acme United Corporation (001180207)

Registrant - Safetec of America, Inc. (874965262)

Establishment				
Name	Address	ID/FEI	Business Operations	
Safetec of America, Inc.		874965262	MANUFACTURE(0924-5701)	

Revised: 5/2012 Acme United Corporation