FIRST AID AND BURN- benzalkonium chloride and 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

External analgesic

Uses

first aid to help prevent infection and for the temporary relief of itching associated with

- minor cuts
- scrapes
- burns

Warnings

For external use only

Do not use

- in the eyes or apply over large areas of the body
- longer than 1 week unless directed by a doctor
- in large quantities, particularly over raw surfaces or blistered areas

Ask a doctor before use if you have deep or puncture wounds, animal bites, or serious burns

When using this product avoid contact with eyes

Stop use and ask a doctor if

- condition worsens or persists for more than 7 days
- clears up and occurs 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

- adults and children 2 years of age and older:
- clean the affected area
- apply a small amount of this product to the area 1 to 3 times daily
- may be covered with a sterile bandage
- children under 2 years of age: consult a doctor

Other information

- store at room temperature
- do not use if packet is opened or torn

Inactive ingredients

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

Questions? 1-800-835-2263

REORDER
www.PhysiciansCareFirstAid.com
1 800 835 2263

PRINCIPAL DISPLAY PANEL – 0.9 gram packet

NDC 0924-5701-01

PhysiciansCARE

Burn Cream

0.9 g (1/32 oz.)

Acme United Corporation

Fairfield, CT 06824 **800-835-2263**

NDC 0924-5701-01

PhysiciansCARE®

Burn Cream

0.9 g (1/32 oz.)

Acme United Corporation
Fairfield, CT 06824 **800-835-2263**

Drug Facts

Active ingredient	Purpose
Benzalkonium Chloride 0.13%	First Aid Antiseptic
Lidocaine HCl 0.5%	Topical Analgesic

Uses ■ temporary relief of pain associated with minor cuts, scrapes, burns ■ helps protect against harmful bacteria

Warnings
For external use only ▶

Drug Facts (continued)

Warnings (continued)
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

Keep out of reach of children
If ingested contact a Poison Control Center right away.

Directions ■ clean affected area ■ apply small amount not more than 3 times daily ■ may be covered with a sterile bandage.

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

PRINCIPAL DISPLAY PANEL – 10 count box

PhysiciansCARE

Burn Cream

Benzalkonium chloride First aid antiseptic
Lidocaine HCl External Analgesic

10 Single use Packets 0.9 g each

Reorder No. 51014

ANSI Z308.1

Drug Facts

Active ingredients *(In each gram)* — **Purpose**

Benzalkonium chloride 0.13 % ..... First aid antiseptic
Lidocaine HCL 0.5 % ..... External analgesic

Uses first aid to help prevent infection and for the temporary relief of itching associated with
• minor cuts • scrapes • burns

Warnings

For external use only

Do not use • in the eyes or apply over large areas of the body • longer than 1 week unless directed by a doctor • in large quantities, particularly over raw surfaces or blistered areas

Ask a doctor before use if you have deep or puncture wounds, animal bites, or serious burns

When using this product avoid contact with eyes

Stop use and ask a doctor if • condition worsens or persists for more than 7 days
• clears up and occurs 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 • adults and children 2 years of age and older:
• clean the affected area • apply a small amount of this product on the area 1 to 3 times daily
• may be covered with a sterile bandage • children under 2 years of age: consult a doctor

Other information • store at room temperature • do not use if packet is opened or torn

Drug Facts *(continued)*

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

Questions? 1-800-835-2263

REORDER

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1 800 835 2263

0 73577 51014 2

ANSI Z308.1

Burn Cream

10 Single use Packets

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	**DEA Schedule**	

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: ZY81Z83H0X)	
alcohol (UNII: 3K9958V90M)	
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
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:0924-5701-04	10 in 1 BOX		
1	NDC:0924-5701-01	0.9 g in 1 PACKET		
2	NDC:0924-5701-09	10 in 1 BOX		
2	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	01/27/2012	

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)