

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

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

Warnings

For external use only

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 – 0.9 gram packet

NDC 0924-5701-01

Physicians CARE

Burn Cream

0.9 g (1/32 oz.)

Acme United Corporation

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

NDC 0924-5701-01



Burn Cream

0.9 g (1/32 oz.)

Acme United Corporation

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

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
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 – Physicians Care bag (0924-5701-03)

Item # 806031

Physicians CARE

**FIRST AID & BURN
CREAM PACKETS**

ANSI Z308.1-2003R

Contents: 6 Single Use Packets

0.9 gr. (1/32 fl. oz.)

See reverse for Drug Facts.

Distributed by **Acme United Corporation**

Fairfield, CT 06824 · 800-835-2263

Item # 806031



FIRST AID & BURN CREAM PACKETS

ANSI Z308.1-2003R

Contents: 6 Single Use Packets

0.9 gr. (1/32 fl. oz.)

See reverse for Drug Facts.

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

Drug Facts

Active ingredients

Benzalkonium Chloride 0.13% First Aid Antiseptic
Lidocaine HCl 0.5%..... Topical Analgesic

Purpose

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,

Drug Facts (continued)

Warnings (continued)

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,

animal bites, serious burns
■ for more than one week unless directed by a
doctor

methylparaben, mineral oil, paraffin, propylparaben,
purified water, white petrolatum, white wax



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

PRINCIPAL DISPLAY PANEL – Pac-Kit bag (0924-5701-02)

Unit 13-006 B

PAC-KIT FIRST AID

**FIRST AID & BURN
CREAM PACKETS**

ANSI Z308.1-2003R

Contents: 6 Single Use Packets

0.9 gr. (1/32 fl. oz.)

See reverse for Drug Facts.

Distributed by **Acme United Corporation**

Fairfield, CT 06824 · 800-835-2263



**UNIT
13-006 B**

FIRST AID & BURN CREAM PACKETS

ANSI Z308.1-2003R
Contents: 6 Single Use Packets
0.9 gr. (1/32 fl. oz.)
 See reverse for Drug Facts.

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

Drug Facts

Active ingredients	Purpose
Benzalkonium Chloride 0.13%	First Aid Antiseptic
Lidocaine HCl 0.5%	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

Drug Facts (continued)

Warnings (continued)

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.

disturbed areas, or on deep puncture wounds,
animal bites, serious burns
■ for more than one week unless directed by a
doctor

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



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

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: ZY81Z83H0X)	
alcohol (UNII: 3K9958V90M)	
methylparaben (UNII: A218C7H19T)	
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:0924-5701-02	6 in 1 BAG		
1	NDC:0924-5701-01	0.9 g in 1 PACKET		
2	NDC:0924-5701-03	6 in 1 BAG		
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

Revised: 1/2012

Acme United Corporation