

FIRST AID ONLY FIRST AID/BURN- lidocaine hydrochloride and benzalkonium chloride cream

Acme United Corporation

First Aid Only First Aid/Burn Cream

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 pain and itching associated with minor: •cuts •scrapes •burns.

WARNINGS

For external use only.

Do not use ■in the eyes ■over large areas of the body ■in large quantities, particularly over raw surfaces or blistered areas ■if you are allergic to any of the ingredients ■on deep puncture wounds, animal bites, or serious burns

- **Stop use and ask a doctor if ■condition worsens or clears up and occurs again within a few days ■symptoms persist for more than 7 days ■a rash or allergic reaction occurs**

Keep out of reach of children.

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

DIRECTIONS

Adults - Clean ■the affected area, apply a small amount of product (equal to the surface area of a fingertip) 1 to 3 times daily.

Children under 2- Consult a doctor

OTHER INFORMATION

Store in a cool dry area 150 – 250C (590 – 770F)

INACTIVE INGREDIENTS

butylated hydroxytoluene, ceteth-20, cetostearyl alcohol, dimethicone, glycerin, glyceryl monostearate, isopropyl myristate, methylcellulose, purified water, sodium EDTA, methylparaben sodium, propylparaben sodium

Questions 1.800.835.2263

carton label

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 pain and itching associated with minor: ■ cuts ■ scrapes ■ burns	
Warnings For external use only. Do not use ■ in the eyes ■ over large areas of the body ■ in large quantities, particularly over raw surfaces or blistered areas ■ if you are allergic to any of the ingredients ■ on deep puncture wounds, animal bites, or serious burns Stop use and ask a doctor if ■ condition worsens or clears up and occurs again within a few days ■ symptoms persist for more than 7 days Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions Adults Children under 2	Clean the affected area, apply a small amount of this product (equal to the surface area of a fingertip) 1 to 3 times daily. Consult a doctor
Other Information Store in a cool, dry area 15° - 25° C (59° - 77° F)	
Inactive Ingredients butylated hydroxytoluene, ceteth-20, cetostearyl alcohol, dimethicone, glycerin, glyceryl monostearate, isopropyl myristate, methylcellulose, purified water, sodium EDTA, methylparaben sodium, propylparaben sodium	
Questions 1.800.835.2263	

13-006
BURNS

First Aid/Burn Cream



First Aid/Burn Cream
12 Packets, 0.9g each

13-006
BURNS

13-006
BURNS



First Aid/Burn Cream

Meets ANSI/ISEA Z308.1-2015 Standard

Manufactured for:
Acme United Corporation
1 Waterview Dr, Shelton, CT 06484
www.FirstAidOnly.com
Made in India
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GUJ/DRUGS/G/25/2134



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807710-revA

FIRST AID ONLY FIRST AID/BURN

lidocaine hydrochloride and benzalkonium chloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-5011(NDC:50382-022)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII: 98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5 mg in 1 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)	
METHYLCELLULOSE (25 MPA.S) (UNII: BI55GG2WLI)	
WATER (UNII: 059QF0KO0R)	
EDETATE SODIUM (UNII: MP1J8420LU)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-5011-00	0.9 g in 1 PACKET; Type 0: Not a Combination Product	08/30/2021	
2	NDC:0924-5011-02	12 in 1 CARTON	08/30/2021	
2		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:0924-5011-03	25 in 1 CARTON	08/30/2021	
3		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:0924-5011-01	10 in 1 CARTON	08/30/2021	
4		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
5	NDC:0924-5011-04	144 in 1 CARTON	08/30/2021	
5		0.9 g 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 Drug	M017	08/30/2021	

Labeler - Acme United Corporation (001180207)

Establishment			
Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-5011) , repack(0924-5011)

Establishment			
Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-5011) , repack(0924-5011)