

FIRST AID ONLY FIRST AID/BURN- lidocaine hydrochloride, 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

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 at room temperature

Inactive Ingredients

butylated hydroxytoluene, cetostearyl alcohol, dimethicone, edetate sodium, glycerin, glyceryl monostearate, isopropyl myristate, macrogol cetostearyl ether 20, methylcellulose, purified water, sodium methylparaben, sodium propylparaben

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
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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 at room temperature	
Inactive ingredients butylated hydroxytoluene, cetostearyl alcohol, dimethicone, edetate disodium, glycerin, glyceryl monostearate, isopropyl myristate, macrogol cetostearyl ether 20, methylcellulose, purified water, sodium methylparaben, sodium propylparaben	
Questions 1.800.835.2263	

13-006 BURNS

FIRST AID ONLY.

First Aid/Burn Cream

12 Packets, 0.9g each

13-006 BURNS

13-006 BURNS

First Aid/Burn Cream

First Aid/Burn Cream

Manufactured for:
Acme United Corporation
1 WaterView Dr, Shelton, CT 06484
www.FirstAidOnly.com
Made in India
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KD/739

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FIRST AID ONLY FIRST AID/BURN

lidocaine hydrochloride, benzalkonium chloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-5730(NDC:61040-007)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z 41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	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)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
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:0924-5730-00	0.9 g in 1 PACKET; Type 0: Not a Combination Product	10/16/2023	
2	NDC:0924-5730-02	12 in 1 CARTON	10/16/2023	
2		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:0924-5730-03	25 in 1 CARTON	10/16/2023	
3		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	M003	10/16/2023	

Labeler - Acme United Corporation (001180207)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-5730) , repack(0924-5730)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	repack(0924-5730) , relabel(0924-5730)