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

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, methyl paraben sodium, propylparaben sodium

Questions 1.800.835.2263

carton label 

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: 0RE8K4LNJS)	
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 not final	part348	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)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		117825595	relabel(0924-5011) , repack(0924-5011)