

FIRST AID ONLY FIRST AID/ 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.

First Aid Only First Aid/Burn Cream

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

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 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 the reach of children.

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

Other information

Store at room temperature

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

Inactive ingredients

aloe vera, cetyl alcohol, diazolidinyl urea, edetate disodium, glycerin, glyceryl monostearate, methylparaben, mineral oil, polyethylene glycol, propylene glycol, propylparaben, purified water, stearic acid, triethanolamine

Questions?

1-800-835-2263

13-006 BURNS

First Aid/Burn Cream

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| Drug Facts | |
| Active ingredients | Purpose |
| Benzalkonium chloride 0.13% Lidocaine HCl 0.5% | 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 the 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 this 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 aloe vera, cetyl alcohol, diazolidinyl urea, edetate disodium, glycerin, glyceryl monostearate, methylparaben, mineral oil, polyethylene glycol, propylene glycol, propylparaben, purified water, stearic acid, triethanolamine | |
| 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

ANSI/ISEA Z308.1-2015

Manufactured for:
Acme United Corporation
55 Walls Dr, Fairfield, CT 06824
www.FirstAidOnly.com
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BOX13006-revE

Carton Image

| | | | |
|------------------------------------------------------|------------------------|---------------------------|------------------------------|
| FIRST AID ONLY FIRST AID/ BURN | | | |
| benzalkonium chloride, lidocaine hydrochloride cream | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0924-5711(NDC:59898-902) |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |

| | | |
|----------------------------------------------------------------------------------|-----------------------------------|--------------------|
| LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE HYDROCHLORIDE ANHYDROUS | 0.5 g in 100 g |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.13 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------------------------------|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| WATER (UNII: 059QF0KO0R) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----|------------------|------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:0924-5711-04 | 10 in 1 CARTON | 04/08/2019 | |
| 1 | | 0.9 g in 1 PACKET; Type 0: Not a Combination Product | | |
| 2 | NDC:0924-5711-02 | 6 in 1 CARTON | 04/08/2019 | |
| 2 | | 0.9 g in 1 PACKET; Type 0: Not a Combination Product | | |
| 3 | NDC:0924-5711-03 | 6 in 1 BAG | 04/08/2019 | |
| 3 | | 0.9 g in 1 PACKET; Type 0: Not a Combination Product | | |
| 4 | NDC:0924-5711-01 | 0.9 g in 1 PACKET; Type 0: Not a Combination Product | 04/08/2019 | |
| 5 | NDC:0924-5711-05 | 10 in 1 CARTON | 04/08/2019 | |
| 5 | | 0.9 g in 1 PACKET; Type 0: Not a Combination Product | | |
| 6 | NDC:0924-5711-06 | 12 in 1 CARTON | 04/08/2019 | |
| 6 | | 0.9 g in 1 PACKET; Type 0: Not a Combination Product | | |
| 7 | NDC:0924-5711-07 | 20 in 1 CARTON | 04/08/2019 | |
| 7 | | 0.9 g in 1 PACKET; Type 0: Not a Combination Product | | |
| 8 | NDC:0924-5711-08 | 20 in 1 CARTON | 04/08/2019 | |
| 8 | | 0.9 g in 1 PACKET; Type 0: Not a Combination Product | | |
| 9 | NDC:0924-5711-09 | 25 in 1 CARTON | 04/08/2019 | |
| 9 | | 0.9 g in 1 PACKET; Type 0: Not a Combination Product | | |
| 10 | NDC:0924-5711-10 | 25 in 1 CARTON | 04/08/2019 | |
| 10 | | 0.9 g in 1 PACKET; Type 0: Not a Combination Product | | |
| 11 | NDC:0924-5711-11 | 50 in 1 CARTON | 04/08/2019 | |
| 11 | | 0.9 g in 1 PACKET; Type 0: Not a Combination Product | | |
| 12 | NDC:0924-5711-12 | 60 in 1 CARTON | 04/08/2019 | |
| 12 | | 0.9 g in 1 PACKET; Type 0: Not a Combination Product | | |
| 13 | NDC:0924-5711-13 | 144 in 1 CARTON | 04/08/2019 | |

| | | | | |
|------------------------------|-------------------------------------------------|------------------------------------------------------|-----------------------------|---------------------------|
| 13 | | 0.9 g in 1 PACKET; Type 0: Not a Combination Product | | |
| 14 | NDC:0924-5711-14 | 144 in 1 CARTON | 04/08/2019 | |
| 14 | | 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 | | 04/08/2019 | |

Labeler - Acme United Corporation (001180207)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|----------------------------------------|
| Acme United Corporation | | 045924339 | relabel(0924-5711) , repack(0924-5711) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|----------------------------------------|
| Acme United Corporation | | 080119599 | relabel(0924-5711) , repack(0924-5711) |

Revised: 12/2020

Acme United Corporation