

FIRST AID BURN- benzalkonium chloride, lidocaine hydrochloride cream
Honeywell Safety Products USA, Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click [here](#).

0498-0903: First Aid Burn Cream

Active ingredients

Benzalkonium chloride 0.13%

Lidocaine HCl 0.5%

Purpose

First Aid antiseptic

External analgesic

Uses

- prevent skin infection
- for temporary relief of pain associated with minor burns

Warnings

For external use only

Do not use

- in or near the eyes
- if you are allergic to any of the ingredients
- in large areas of the body, particularly over raw surfaces or blistered areas
- for more than 10 days

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occurs again within a few days

Keep out of reach of children

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

Directions

- **adults and children 2 years of age and older:**
- clean the affected area
- apply a small amount of this product (equal to the surface area of the tip of a finger) onto affected area 1 to 3 times daily
- may be covered with a sterile bandage
- **children under 2 years of age:** consult a doctor

Other information

- tamper evident sealed packets
- do not use if packet is opened or torn

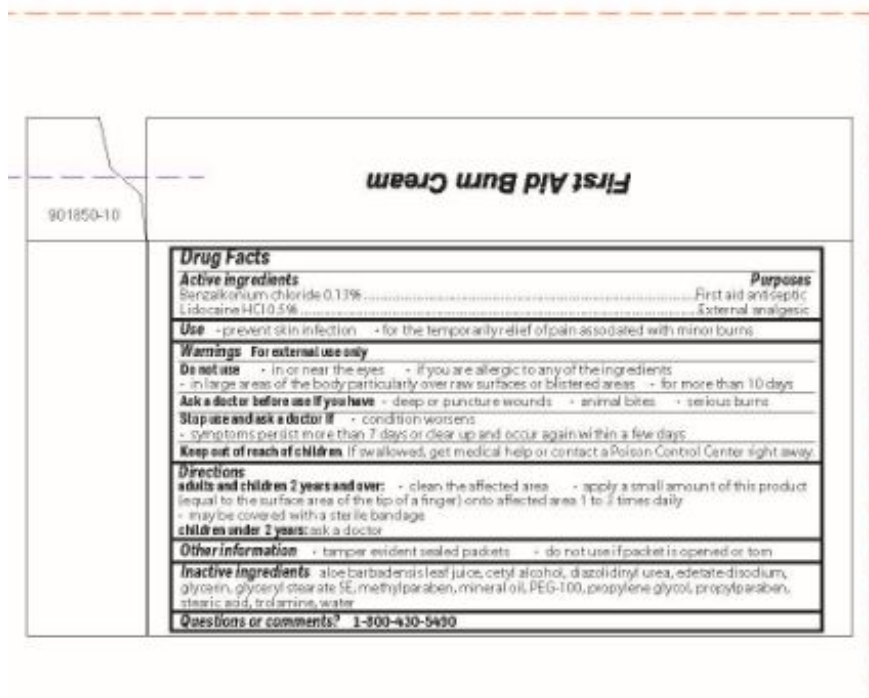
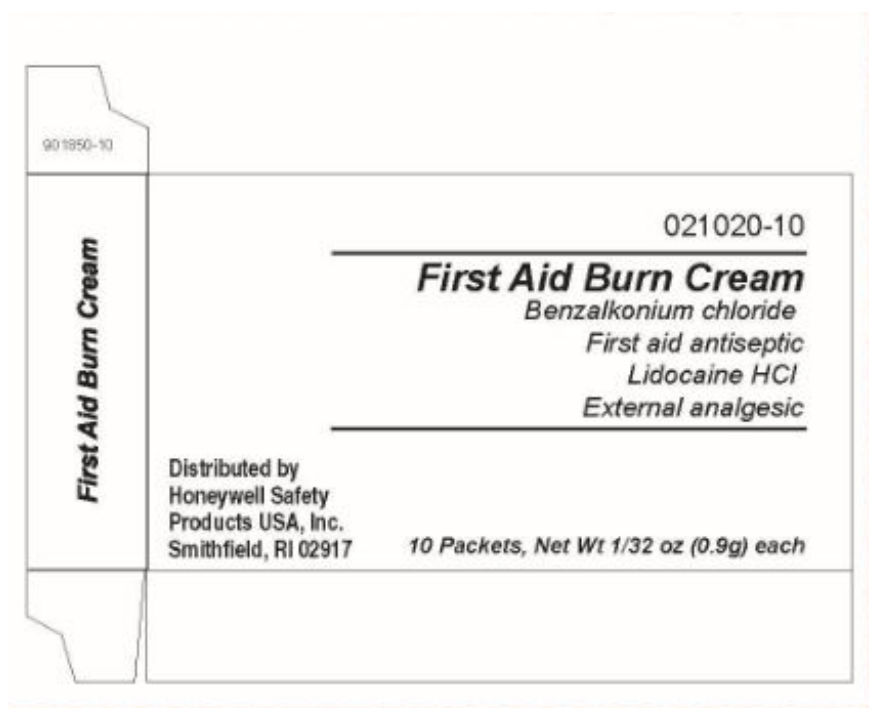
Inactive ingredients

aloe barbadensis juice, cetyl alcohol, diazolidinyl urea, edetate disodium, glycerin, glyceryl stearate SE, methylparaben, mineral oil, PEG-100, propylene glycol, propylparaben, stearic acid, trolamine, water

Questions

1-800-430-5490

Principal Display Panel



FIRST AID BURN

benzalkonium chloride, lidocaine hydrochloride cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0498-0903 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|--|-------------------------|--------------------|
| LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE HYDROCHLORIDE | 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 |
|--|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| WATER (UNII: 059QF0KO0R) | |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0498-0903-34 | 10 in 1 BOX, UNIT-DOSE | 12/20/2017 | |
| 1 | | 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 |
|--------------------------|--|----------------------|--------------------|
| unapproved drug other | | 12/20/2017 | |

Labeler - Honeywell Safety Products USA, Inc (118768815)

Registrant - Honeywell Safety Products USA, Inc (118768815)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|------------------------|
| Water-Jel Technologies | | 155522589 | manufacture(0498-0903) |