

BURN RELIEF SIGNATURE CARE- lidocaine 0.50% spray

Better Living

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.

Drug Facts

| Active ingredient | Purpose |
|---------------------|--------------------|
| Lidocaine 0.5%..... | Topical anesthetic |

Uses

For temporary relief of pain associated with pain or itching due to : minor burns, sunburns, minor cuts, insect bites, skin irritation

Warnings

For external use only.

Flammable: Do not use while smoking or near heat or flame

When using this product • use only as directed • avoid contact with eyes

Do not puncture or incinerate. Contents under pressure. Do not store at temperature above 120F

Stop use and ask a doctor if • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately

Directions

Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age: consult a doctor.

Inactive ingredients

Aloe Barbadensis Leaf Extract

Carbomer

Diazolidinyl Urea

Disodium Cocoamphodipropionate

Disodium EDTA

Glycerin

Methylparaben

Propylene Glycol

Propylparaben

SD Alcohol 40

Simethicone

Tocopheryl Acetate

Triethanolamine



Quality Guaranteed

Burn Relief Spray

MAXIMUM STRENGTH
Lidocaine 4%

- Cooling, moisturizing relief
- No-rub application
- For sunburns, minor cuts & scrapes, skin irritation & insect bites
- With aloe vera

NET WT 4.5 OZ (127 g)

Drug Facts

Active ingredient Purpose
Lidocaine 4%.....External analgesic

Uses Temporarily relieves pain and itching due to:
 • sunburn • minor burns • minor cuts • scrapes
 • insect bites • minor skin irritations

Warnings

For external use only.

Flammable: Do not use while smoking or near heat or flame

Do not use in large quantities, particularly over raw surfaces or blistered areas

When using this product • keep out of eyes. • use only as directed. • do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

Stop use and ask doctor if • condition gets worse • symptoms last more than 7 days • symptoms clear up and occur again in a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • apply to affected area not more than 3 to 4 times daily
 • children under 2 years of age: ask a doctor • to apply to face, spray into palm of hand and gently apply

Inactive ingredients Alcohol Denat., Aloe Barbadensis Leaf, Carbomer, Chamomilla Recutita (Matricaria) Flower Extract, Cucumis Sativus (Cucumber) Fruit Extract, Diazolidinyl Urea, Disodium Cocoamphodipropionate, Disodium EDTA, Glycerin, Propylene Glycol, Simethicone, Tocopheryl Acetate, Triethanolamine, Water.



DISTRIBUTED BY:
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BURN RELIEF SIGNATURE CARE

lidocaine 0.50% spray

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:21130-761 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| Lidocaine (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | Lidocaine | 0.5 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| Diazolidinyl Urea (UNII: H5RIZ3MPW4) | |
| Disodium Cocoamphodipropionate (UNII: 6K8PRP397M) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| Glycerin (UNII: PDC6A3C0OX) | |
| Methylparaben (UNII: A218C7HI9T) | |

| | |
|--|--|
| Propylene Glycol (UNII: 6DC9Q167V3) | |
| Propylparaben (UNII: Z8IX2SC1OH) | |
| Alcohol (UNII: 3K9958V90M) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:21130-761-04 | 127 g in 1 CAN; Type 0: Not a Combination Product | 03/30/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 03/30/2018 | |

Labeler - Better Living (009137209)

Registrant - Product Quest Mfg (927768135)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|---|
| Product Quest Mfg | | 927768135 | manufacture(21130-761) , label(21130-761) |

Revised: 1/2018

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