BURN RELIEF- lidocaine 0.5% spray Product Quest Mfg

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% External analgesic

Uses

Temporarily relieves pain and itching due to

- sunburn minor burns minor cuts scrapes
- insect bites minor skin irritation

Warnings

For external use only

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

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

When using this product

- keep out of your eyes
- use only as directed
- do not puncture or incinerate. Contents under pressure. Do not store at temperature above 120F.

Stop use and ask a doctor if

- condition gets worse
- symptoms last more than 7 days
- symptoms clear up and occur again within a few days

Keep out of reach of the children

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

Directions

- shake well
- 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: ask a doctor
- to apply to face, spray into palm of hand and gently apply

Inactive ingredients

Aloe Barbadensis Leaf Juice, Carbomer, Diazolidinyl Urea, Disodium Cocoamphodipropionate, Disodium EDTA, Glycerin, Methylparaben, Propylene Glycol, Propylparaben, SD Alcohol 40, Simethicone, Tocopheryl Acetate, Triethanolamine

Questions and comments?

1-866-483-2846



Since 1933, Scherer Labs™ has been providing Quality, Innovative and Value oriented family-care products.





Burn Relief

Continuous Spray with Aloe Vera

0.5% Lidocaine
For Minor Burns, Cuts,
Scrapes & Itching
Instant Pain Relief with Lidocaine
Sprays at Any Angle

NET WT. 4.5 OZ. (127 g)

MADE IN USA

BURN RELIEF

lidocaine 0.5% spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:64048-5115

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength |
|-----------------|--|-------------------|----------------|
| I | 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 DISO DIUM (UNII: 7FLD91C86K) | |
| Glycerin (UNII: PDC6A3C0OX) | |
| Methylparaben (UNII: A2I8C7HI9T) | |
| Propylene Glycol (UNII: 6DC9Q167V3) | |
| Propylparaben (UNII: Z8IX2SC1OH) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| .ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |

| Packaging | | | | |
|--------------------|---|----------------------|--------------------|--|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 NDC:64048-5115-4 | 127 g in 1 CAN; Type 0: Not a Combination Product | 02/06/2014 | | |

| Marketing Information | | | | |
|---|---------|----------------------|--------------------|--|
| Marketing Category Application Number or Monograph Ci | | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part348 | 02/06/2014 | | |
| | | | | |

Labeler - Product Quest Mfg (927768135)

Registrant - Product Quest Mfg (927768135)

| Establishment | | | |
|-------------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| Product Quest Mfg | | 927768135 | manufacture(64048-5115), label(64048-5115) |

Revised: 7/2018 Product Quest Mfg