

BIO-SCRIPTIVES LIDUM TOPICAL ANALGESIC- lidocaine cream

Bio-Scriptives, Inc.

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.

Bio-Scriptives Lidum (Lidocaine 4%) Topical Analgesic

Drug Facts

Active Ingredients

Lidocaine 4%

Purpose

Local Analgesic

Uses

For the temporary relief of pain and itching due to:

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

Warnings

For external use only

When using this product

- avoid contact with the eyes
- do not use in large quantities, particularly over raw surfaces or blistered areas

Stop use and ask doctor if:

- condition worsens
- symptoms persist for more than 7 days
- symptoms 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 right away.

Directions

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

daily.

- Children under 2 years of age: Consult a doctor.

Inactive Ingredients

Aloe, Water, Cholesterol, Isopropyl Myristate, Aqua Caprylic/Capric Triglyceride, Propylene Glycol, Hydrogenated Phosphatidylcholine, Glyceryl Stearate, PEG-100 Stearate, Arginine HCL, Ethyl Oleate, Propylene Glycol, Tocophersolan, Cetyl Alcohol, Triethanolamine, Xanthan Gum, Tocopherol, Allantoin, Aloe Barbadensis Leaf, Methylisothiazolinone, Methyl Nicotinate.

Package and Label Images

|  <p>BIO SCRIPTIVES[®] Lidum[®] (Lidocaine 4%) Topical Analgesic Cream Derma-Release[®] Technology Net Wt 2 oz (56 g)</p> | <p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Lidocaine 4%</td><td>Local Anesthetic</td></tr></tbody></table> <p>Uses For the temporary relief of pain and itching due to:</p> <ul style="list-style-type: none">■ scrapes ■ minor skin irritations ■ minor burns■ sunburn ■ minor cuts ■ insect bites <p>Warnings For external use only</p> <p>When using this product</p> <ul style="list-style-type: none">■ avoid contact with the eyes■ do not use in large quantities, particularly over raw surfaces or blistered areas. <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none">■ condition worsens■ symptoms persist for more than 7 days■ symptoms clear up and occur again within a few days <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none">■ Adults and children 2 years of age and older: Apply to the affected area not more than 3 to 4 times daily.■ Children under 2 years of age: Consult a doctor. <p>Inactive ingredients: Aloe, Water, Cholesterol, Isopropyl Myristate, Aqua, Caprylic/Capric Triglyceride, Propylene Glycol, Hydrogenated Phosphatidylcholine, Glyceryl Stearate, PEG-100 Stearate, Arginine HCL, Ethyl Oleate, Propylene Glycol, Tocophersolan, Cetyl Alcohol, Triethanolamine, Xanthan Gum, Tocopherol, Allantoin, Aloe Barbadensis Leaf, Methylisothiazolinone, Methyl Nicotinate</p> | Active ingredient | Purpose | Lidocaine 4% | Local Anesthetic |
|--|--|-------------------|---------|--------------|------------------|
| Active ingredient | Purpose | | | | |
| Lidocaine 4% | Local Anesthetic | | | | |

BIO-SCRIPTIVES®
Lidum®
(Lidocaine 4%)

Topical Analgesic
Cream

Derma-Release®
Technology

Net Wt 2 oz (56 g)

BIO-SCRIPTIVES®
Lidum®
(Lidocaine 4%)

Topical Analgesic
Cream

Derma-Release®
Technology

Distributed by BioChemics
dba Bio-Scriptives
88 Rosewood Dr. #260
Danvers, MA 01923

BIO-SCRIPTIVES®
Lidum®
(Lidocaine 4%)

Topical Analgesic
Cream

Derma-Release®
Technology

Questions?
1-978-750-0790
www.bioscriptives.com

Drug Facts

| Active ingredient | Purpose |
|-------------------|------------------|
| Lidocaine 4% | Local Anesthetic |

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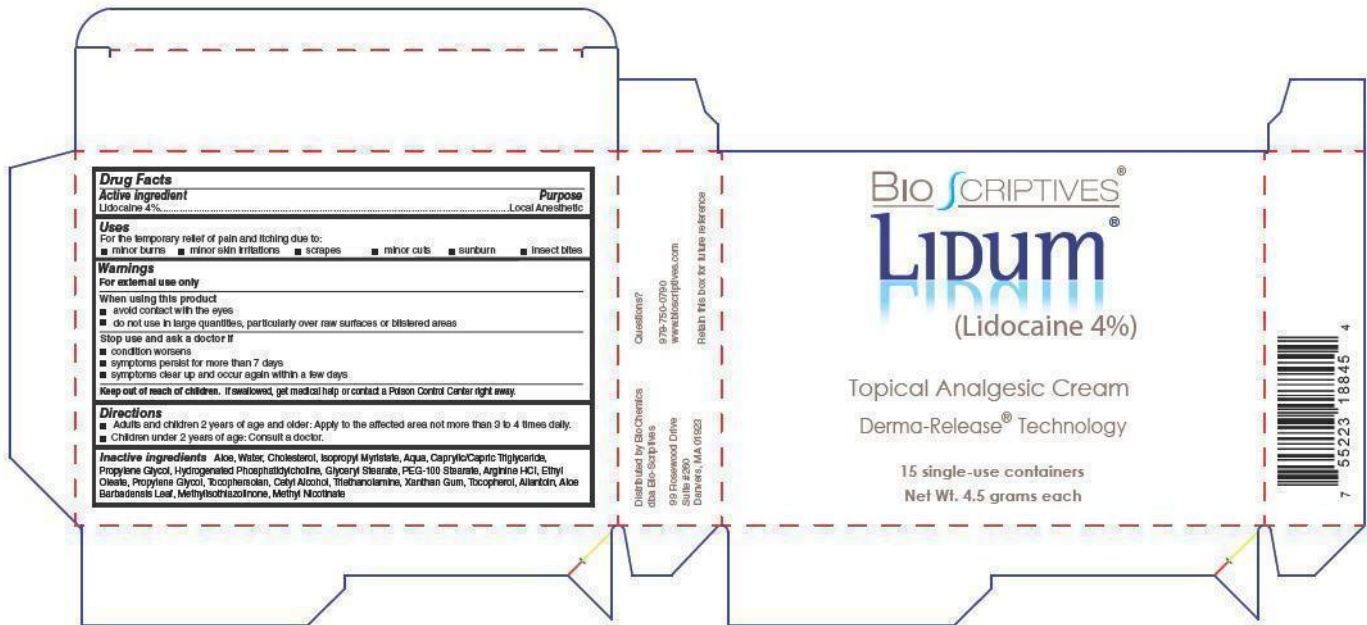


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Lidum®

(Lidocaine 4%)

Net Wt. 4.5 grams



BIO-SCRIPTIVES LIDUM TOPICAL ANALGESIC

lidocaine cream

Product Information

| | | | |
|-------------------------|-------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:60608-017 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 2.8 g in 56 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| WATER (UNII: 059QF0K00R) | |
| CHOLESTEROL (UNII: 97C5T2UQ7J) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |

| |
|--|
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) |
| HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N) |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) |
| POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A) |
| ARGININE HYDROCHLORIDE (UNII: F7LTHIE20Y) |
| ETHYL OLEATE (UNII: Z2Z439864Y) |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) |
| TOCOPHERSOLAN (UNII: O03S90U1F2) |
| CETYL ALCOHOL (UNII: 936JST6JCN) |
| TROLAMINE (UNII: 9O3K93S3TK) |
| xanthan gum (UNII: TTV12P4NEE) |
| ALPHA-TOCOPHEROL (UNII: H4N855PNZ1) |
| ALLANTOIN (UNII: 344S277G0Z) |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) |
| METHYL NICOTINATE (UNII: 7B1AVU9DJN) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:60608-017-01 | 1 in 1 BOX | | |
| 1 | NDC:60608-017-00 | 56 g in 1 TUBE | | |
| 2 | NDC:60608-017-03 | 15 in 1 BOX | | |
| 2 | NDC:60608-017-02 | 4.5 g in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part346 | 03/07/2012 | |

Labeler - Bio-Scriptives, Inc. (802946426)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|---------------------|
| Coastal Products Company | | 782445688 | manufacture |

Revised: 3/2012

Bio-Scriptives, Inc.