

ZIMS LIDO FREEZE- menthol, unspecified form and lidocaine gel
NATURAL ESSENTIALS, 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.

Drug Facts

Active ingredients

Lidocaine 4%

Menthol USP 1 %

Purpose

Topical Analgesic

Topical Analgesic

Use

- For the temporary relief of pain.

Warnings

For external use only

Do not use

- if you are allergic to any ingredient in this product
- on large areas of the body or on cut, irritated or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor

Ask a doctor or pharmacist before use if you are

- using blood thinning medications, steroids or non-steroidal anti-inflammatory drugs (NSAIDS)

When using this product

- do not use other topical products
- avoid contact with eyes or mucous membranes
- do not bandage tightly or apply local heat (such as heating pads) to area of use or with a medicated patch
- keep away from excessive heat

Stop use and ask a doctor if

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days
- you experience signs of skin injury, such as pain, swelling or blistering where product was applied

If pregnant or breast feeding ask a physician before use.

Keep out of reach of children. If put in the mouth, get medical help or contact a poison control center

right away.

Directions

Adults/children 12 years and older

- Apply to affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period
- After applying, wash hands with soap and water
- Under age 12, consult a physician before use

Other information

Store at room temperature - do not exceed 86° Fahrenheit, 30° Celsius

Inactive ingredients

Aloe Barbadosis Leaf Extract, Arnica Extract, Camphor, Carbomer, Deionized Water, Disodium EDTA, Glycerine, Isopropyl Alcohol, Propylene Glycol.

Principal Display Panel - 10mg of Menthol and 40 mg of Lidocaine Canister Label

ZIM'S

LIDO-

FREEZE

LIDOCAINE & MENTHOL

PAIN RELIEF

Lidocaine & Menthol
formula in as easy to use
roll-on applicator

Nature Science

89 mL (3 fl oz)

Drug Facts

| Active ingredients | Purpose |
|----------------------|-------------------|
| Lidocaine 4%..... | Topical Analgesic |
| Menthol USP 1% | Topical Analgesic |

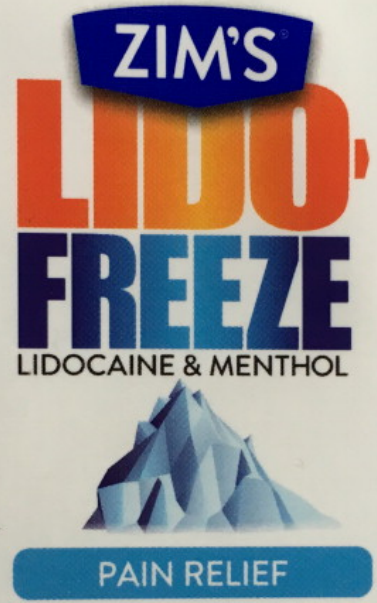
Use
 ■ For the temporary relief of pain.

Warnings
For external use only

Do not use
 ■ if you are allergic to any ingredient in this product
 ■ on large areas of the body or on cut, irritated or swollen skin
 ■ on puncture wounds
 ■ for more than one week without consulting a doctor

Ask a doctor or pharmacist before use if you are
 ■ using blood thinning medications, steroids or non-steroidal anti-inflammatory drugs (NSAIDs)

NDC #66902-230-03



Lidocaine & Menthol formula in an easy to use roll-on applicator



89 mL (3 fl oz)

Drug Facts (Continued)

When using this product
 ■ do not use other topical products
 ■ avoid contact with eyes or mucous membranes
 ■ do not bandage tightly or apply local heat (such as heating pads) to area of use or with a medicated patch
 ■ keep away from excessive heat

Stop use and ask a doctor if
 ■ condition worsens ■ redness is present
 ■ irritation develops
 ■ symptoms persist for more than 7 days or clear up and occur again within a few days
 ■ you experience signs of skin injury, such as pain, swelling or blistering where product was applied

If pregnant or breast feeding ask a physician before use.
Keep out of reach of children. If put in the mouth, get medical help or contact a poison control center right away.

Directions Adults/children 12 years and older
 ■ Apply to affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period
 ■ After applying, wash hands with soap and water
 ■ Under age 12, consult a physician before use

Other information Store at room temperature – do not exceed 86° Fahrenheit, 30° Celsius.

Inactive ingredients Aloe Barbadosis Leaf Extract, Arnica Extract, Camphor, Carbomer, Deionized Water, Disodium EDTA, Glycerine, Isopropyl Alcohol, Propylene Glycol.

Distributed by Perfecta Products, Inc.®
 North Lima, Ohio 44452
 (800) 319-2225 • www.ZimsUSA.com
 ©2016 Perfecta Products, Inc. Made in USA

ZIMS LIDO FREEZE

menthol, unspecified form and lidocaine gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:66902-230 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|---------------|
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL, UNSPECIFIED FORM | 10 mg in 1 mL |
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 40 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| ARNICA MONTANA (UNII: O80TY208ZW) | |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) | |
| CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |

| | |
|---|--|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:66902-230-03 | 89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product | 08/01/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 08/01/2016 | |

Labeler - NATURAL ESSENTIALS, INC (947484713)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| NATURAL ESSENTIALS, INC | | 947484713 | MANUFACTURE(66902-230) |

Revised: 8/2016

NATURAL ESSENTIALS, INC