

PAIN RELIEF BODY AUDACIOUS WRECK RELIEF- lidocaine spray
Australis Capital (Nevada) 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 ingredient

Lidocaine 4 %

Purpose

Topical Anesthetic

Uses

For temporary relief of pain and itching due to :

- sunburn
- scrapes
- insect bites
- minor skin irritations

Warnings

For external use only

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

Do not use

to wounds or damaged skin • do not use in large quantities, particularly over raw surface or blistered areas.

When using this product

- avoid contact with eyes
- use only as directed
- do not puncture or incinerate
- content under pressure, do not store at temperature above 120 °F

Stop use and ask doctor if

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

If accidentally ingested get medical help or contact a Poison Control Center immediately

Direction

- Adults and children 2 years of age and older: apply to affected area not more than 3-4 times daily
- Children under 2 years old: consult a doctor

Inactive ingredients

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



| Drug Facts | |
|---|--------------------|
| Active ingredient | Purpose |
| Lidocaine 4%..... | Topical anesthetic |
| Uses Temporary relief of pain and itching due to: • sunburn • scrapes • insect bites • minor skin irritations | |
| Warnings For external use only. | |
| Flammable • keep away from fire or flame | |
| Do not use in large quantities, particularly over raw surfaces and blistered areas | |
| When using this product • avoid contact with eyes • use only as directed • do not puncture or incinerate, contents under pressure • do not store at temperature above 120° F | |
| Stop use and ask doctor if • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days. | |
| If pregnant or breastfeeding, ask a health professional before use. | |
| 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 affected area no more than 3 to 4 times daily. Children under 2 years of age: consult a doctor | |
| Inactive ingredients Alcohol Denat., Aloe Barbadosensis Leaf Extract, 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, Whole Hemp Extract (Isolate). | |
| Questions or comments? 1-800-285-3805 | |



PAIN RELIEF BODY AUDACIOUS WRECK RELIEF

lidocaine spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:82212-001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 4 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALCOHOL (UNII: 3K9958V90M) | |
| ALOE (UNII: V5VD430YW9) | |
| CARBOMER 940 (UNII: 4Q93RCW27E) | |
| MATRICARIA CHAMOMILLA FLOWERING TOP (UNII: 3VNC7T6Z02) | |
| CUCUMBER (UNII: YY7C30VXJT) | |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) | |

| | |
|--|--|
| DISODIUM COCOAMPHODIPROPIONATE (UNII: 6K8PRP397M) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |
| CANNABIS SATIVA WHOLE (UNII: B5ONF538PB) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:82212-001-03 | 142 g in 1 CAN; Type 0: Not a Combination Product | 11/08/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 11/08/2021 | |

Labeler - Australis Capital (Nevada) Inc. (081483723)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|------------------------|
| Inspec Solutions LLC | | 081030372 | manufacture(82212-001) |

Revised: 1/2022

Australis Capital (Nevada) Inc.