

DERMANUMB ANALGESIC- lidocaine hcl gel
A.T.S. Laboratories, LLC

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.

DermaNumb Gel

Active Ingredients

Lidocaine HCL 4.0% w/w

Purpose

External Analgesic

Uses

For temporary relief of pain and itching associated with minor cuts or minor skin irritations.

Warnings

For external use only

Avoid contact with eyes

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

Stop use and ask doctor if

- Condition worsens, or if symptoms persist for more than 7 days or clear up and occur again with a few days. Discontinue use.

Keep out of reach of children

- If product is swallowed, get medical help or contact a poison control center right away.

Directions

For adults and children two-years or older: Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: consult a physician.

Inactive Ingredients

Achillea Millefolium (Yarrow) Extract, Alcohol SDA-40, Aloe Barbadensis Leaf Extract, Capryly Glycol, Carbomer, Disodium EDTA, Glycerin, Menthol, Methylisothiazolinone, Propylene Glycol, Schidigera (Yucca) Root Extract, Triethanolamine, Water.

Other Information

Protect this product from excessive heat and direct sun.

Questions or Comments?

954-492-9898

Drug Facts

| Active Ingredients | Purpose |
|------------------------|--------------------|
| Lidocaine HCL 4.0% w/w | External Analgesic |

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*Manufactured for A.T.S. Laboratories
Deerfield Beach, FL. Made in the USA
954-492-9898 or Dermanumb.com*

DERMA NUMB™ Gel
PAIN RELIEVING
2oz.

DERMANUMB ANALGESIC

lidocaine hcl gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70188-006 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|--------------|
| LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE HYDROCHLORIDE | 40 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 132584PQMO) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) | |
| YUCCA SCHIDIGERA (UNII: 08A0YG3VIC) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70188-006-01 | 57 g in 1 PACKAGE; Type 0: Not a Combination Product | 07/01/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 07/01/2015 | |

Labeler - A.T.S. Laboratories, LLC (080013331)

Revised: 1/2022

A.T.S. Laboratories, LLC