

**EXTRA STRENGTH WOUND CARE- lidocaine hcl cream**

**Ridge Properties**

*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.*

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**Directions: Test skin to sensitivity prior to procedure. Apply generously to Affected area as needed for pain. Discontinue use if sensitivity occurs. Not for use on face.**

**Warning - Keep out of reach of children - For external use only - Avoid contact with the eyes**

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*Purpose:*

**Topical Anesthetic**

**Uses: Temporarily relieves pain**

*Active ingredients:*

**Lidocaine HCL                      4%**

# Inactive Ingredients:

Water, Witch Hazel, Kava kava, Organic Alcohol, Propolis, Yarrow, Nutmeg, Copaiba Balsam, BTMS 50 (A natural extract of the Colza Seed)

|   |   |   |   |  |   |  |
|---|---|---|---|--|---|--|
| <p>FDA Registered<br/>NDC # 69804-054-02</p> <p><b>Active ingredients:</b><br/>Lidocaine HCL 4%</p> <p><b>Purpose:</b><br/>Topical Anesthetic</p> <p><b>Drug Facts:</b><br/>For professional use only</p> | <p><b>Do Not Use</b> if you have any known allergy to any of the ingredients in this product. Discontinue use and seek medical attention should any occur</p> <p><b>Uses:</b> Temporarily relieves pain</p> | <p><b>Directions:</b> Test skin to sensitivity prior to procedure. Apply generously to Affected area as needed for pain. Discontinue use if sensitivity occurs. Not for use on face.</p> <p><b>2 OZ Balm</b></p>  <p>6 45338 89055 0</p> |  | <p><b>Stop use and ask a doctor if</b> - Skin becomes irritated - Condition worsens or symptoms last longer than 7 days - Symptoms clear up then reoccur within a few days</p> <p>Warning: Keep out of reach of children - For external use only - Avoid contact with the eyes</p> | <p><b>Other information:</b><br/>This product was manufactured by Pain Relief Naturally. For contact info please visit <a href="http://WWW.NATURALLYHL.COM">WWW.NATURALLYHL.COM</a></p> | <p><b>Inactive Ingredients:</b><br/>Water, Witch Hazel, Organic Alcohol, Kava Kava, Yarrow, Nutmeg, Propolis, (BTMS 50 -A Natural Extract of The Colza Seed)</p> |
|---|---|---|---|--|---|--|

## EXTRA STRENGTH WOUND CARE

lidocaine hcl cream

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:69804-054 |
| Route of Administration | TOPICAL        |                    |               |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength                 | Strength         |
|--|-----------------------------------|------------------|
| LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE HYDROCHLORIDE ANHYDROUS | 40 mg in 1000 mg |

## Inactive Ingredients

| Ingredient Name                                 | Strength          |
|---|-------------------|
| PROPOLIS WAX (UNII: 6Y8XYV2NOF)                 | 40 mg in 1000 mg  |
| PIPER METHYSTICUM WHOLE (UNII: 3P306S300W)      | 190 mg in 1000 mg |
| WITCH HAZEL (UNII: 101I4J0U34)                  | 400 mg in 1000 mg |
| COPAIBA OIL (UNII: 64VX45Y68N)                  | 90 mg in 1000 mg  |
| BEHENTRIMONIUM METHO SULFATE (UNII: 5SHP745C61) | 120 mg in 1000 mg |
| NUTMEG OIL (UNII: Z1CLM48948)                   | 60 mg in 1000 mg  |
| ACHILLEA MILLEFOLIUM OIL (UNII: 97P5D0WG43)     | 60 mg in 1000 mg  |

## Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69804-054-06 | 14200 mg in 1 JAR; Type 0: Not a Combination Product  | 05/01/2017           |                    |
| 2 | NDC:69804-054-05 | 28500 mg in 1 JAR; Type 0: Not a Combination Product  | 05/01/2017           |                    |
| 3 | NDC:69804-054-02 | 56700 mg in 1 JAR; Type 0: Not a Combination Product  | 05/01/2017           |                    |
| 4 | NDC:69804-054-03 | 113400 mg in 1 JAR; Type 0: Not a Combination Product | 05/01/2017           |                    |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348                                  | 05/01/2017           |                    |

**Labeler** - Ridge Proeprties (029478762)

## Establishment

| Name             | Address | ID/FEI    | Business Operations    |
|------------------|---------|-----------|------------------------|
| ridge properties |         | 029478762 | manufacture(69804-054) |

Revised: 4/2017

Ridge Proeprties