**ZONE 2- lidocaine hcl, epinephrine gel**
**Dermal Source, Inc.**

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**Drug Facts - For use by licensed professionals only.**

| ***Active Ingredients (in each cc)*** | | ***Purpose*** |
|---|---|---|
| Lidocaine HCL | 4% | Topical Anesthetic |
| Epinephrine | 0.01% | Vasoconstrictor |

**Uses:** Temporarily relieves local pain and swelling on irritated hemorrhoidal tissue or other anorectal disorders.

***WARNINGS: External use only.***
**Do not swallow. Keep out of children's reach.**

**Do not use if you have**
- A history of severe liver disease or impairment.
- A known allergy or sensitivity to any of the components of this product. If sensitivity occurs, consult a doctor if condition worsens or does not improve in seven days, or clears up and occurs again within a few days. Do not use in large quantities, particularly over raw surfaces or blistered areas.

**Do not use** if pregnant or nursing. In case of accidental contact with eyes, rinse immediately with copious amounts of eyewash. Seek care by an eye care physician. If accidentally swallowed, get medical help immediately.

**When using this product**
- You may notice temporary blanching, skin irritation or sensitivity of the skin where gel is applied
- You may not have pain - avoid sources of heat or injury
- You may have delayed swelling after drug is dissipated

**Directions: Sensitivity test advised prior to use.**

Apply sparingly to affected area up to four times daily and cover with occlusive dressing. Wait until anesthetic effect occurs (2-5 minutes). Remove product.

***Inactive Ingredients:*** Purified Water, Ethoxydiglycol, Propylene Glycol, Hydroxyethylcelluse, Sodium Metabisulfite, Diazolidinyl Urea, Disodium EDTA, Methyl Paraben, Propyl Paraben, and Citric Acid.

***Other information*:** Store in a cool dark place or refrigerate. Discard after expiration date.

***Questions?*** Contact distributor on product label for further questions.

**PRINCIPAL DISPLAY PANEL**

NDC Code: 80069-015-01

**MAXIMUM**
**Zone 2**

**TOPICAL ANALGESIC**

**1 oz**.

**for use during a pain sensitive procedure**

Distributed by: **DERMAL SOURCE**
Portland, OR 97232
**www.dermalsource.com**
**1-866-568-3223**


## ZONE 2

lidocaine hcl, epinephrine gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:80069-015 |
| **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 1 mL |
| **Epinephrine** (UNII: YKH834O4BH) (Epinephrine - UNII:YKH834O4BH) | Epinephrine | 0.1 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **Water** (UNII: 059QF0KO0R) | |
| **Diethylene Glycol Monoethyl Ether** (UNII: A1A1I8X02B) | |
| **Propylene Glycol** (UNII: 6DC9Q167V3) | |
| **Hydroxyethyl Cellulose, Unspecified** (UNII: T4V6TWG28D) | |
| **Sodium Metabisulfite** (UNII: 4VON5FNS3C) | |
| **Diazolidinyl Urea** (UNII: H5RIZ3MPW4) | |
| **Edetate Disodium Anhydrous** (UNII: 8NLQ36F6MM) | |
| **Methylparaben** (UNII: A2I8C7HI9T) | |
| **Propylparaben** (UNII: Z8IX2SC1OH) | |
| **Citric Acid Monohydrate** (UNII: 2968PHW8QP) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:80069-015-01 | 29.5735 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/01/2022 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M015 | 04/01/2022 | |

## Labeler - Dermal Source, Inc. (183535629)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| HTO Nevada, Inc. (dba Kirkman) | | 117115846 | manufacture(80069-015) |

Revised: 5/2024 Dermal Source, Inc.