

**NUMB 520- lidocaine cream**  
**Ebanel Laboratories, Inc**

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**Active Ingredient Purpose**

Lidocaine 5% .....Local Anesthetic

**Uses**

- For the temporary relief of local and anorectal itching and discomfort associated with anorectal disorders and anorectal inflammation.
- For the temporary relief of pain, burning and soreness.

**Warnings** (For external use only)

- If condition worsens or does not improve within 7 days, consult a doctor.
- Do not exceed the recommended daily dosage unless directed by a doctor.
- In case of bleeding, consult a doctor promptly.
- Do not put this product into the rectum by using fingers or any mechanical device or applicator.
- Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and consult a doctor.

**Directions**

- Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product. Children under 12 years of age: consult a doctor.
- Apply externally to the affected area up to 6 times daily.

**Other Information**

- Keep away from direct sunlight or heat.
- Store at room temperature 15°-30°C (59°-86°F).
- This package is child-resistant. Keep out of reach of children.
- In case of accidental overdose or ingestion, call a doctor or poison control center immediately.
- Do not use this product if seal is broken or missing.

**Inactive Ingredients**

Allantoin, Aloe Barbadensis Leaf Juice, Benzyl Alcohol, Carbomer, Cholesterol, Dimethyl Isosorbide, Disodium EDTA, Hydrogenated Polydecene, Lecithin, Neopentyl Glycol Dicaprylate/Dicaprate, Propylene Glycol, Sodium Polyacrylate, Tocopheryl Acetate, Trideceth-6, Triethanolamine, Water

Purpose.....Local Anesthetic

Manufactured for Ebanel Laboratories, Inc.  
1400 W. Lambert Rd., Suite D, Brea, CA 92821  
www.ebanel.com | Made in USA

682017 337807

**DRUG FACTS (Continued)**

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**Ebanel**  
LIPOSOMAL  
**NUMB520**

**5% LIDOCAINE**

**CHILD-RESISTANT PACKAGING**

**Topical Anorectal Cream**  
4.4 oz e 125g

**DRUG FACTS**

| Active Ingredient | Purpose          |
|-------------------|------------------|
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CHILD-RESISTANT PACKAGING

Topical Anorectal Cream

4.4 oz e 125 g

| NUMB 520                                                   |                |                    |               |
|------------------------------------------------------------|----------------|--------------------|---------------|
| lidocaine cream                                            |                |                    |               |
| Product Information                                        |                |                    |               |
| Product Type                                               | HUMAN OTC DRUG | Item Code (Source) | NDC:72654-033 |
| Route of Administration                                    | TOPICAL        |                    |               |
| Active Ingredient/Active Moiety                            |                |                    |               |
| Ingredient Name                                            |                | Basis of Strength  | Strength      |
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) |                | LIDOCAINE          | 50 mg in 1 g  |
| Inactive Ingredients                                       |                |                    |               |
| Ingredient Name                                            |                |                    | Strength      |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)              |                |                    |               |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)  |                |                    |               |
| CHOLESTEROL (UNII: 97C5T2UQ7J)                             |                |                    |               |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLV429K27K)  |                |                    |               |
| WATER (UNII: 059QF0KO0R)                                   |                |                    |               |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62)                       |                |                    |               |
| DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)                     |                |                    |               |
| SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)           |                |                    |               |
| ALLANTOIN (UNII: 344S277G0Z)                               |                |                    |               |

|                                                              |  |
|--------------------------------------------------------------|--|
| <b>TRIETHANOLAMINE</b> (UNII: 9O3K93S3TK)                    |  |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                     |  |
| <b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)                     |  |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                   |  |
| <b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)           |  |
| <b>TRIDECETH-6</b> (UNII: 3T5PCR2H0C)                        |  |
| <b>HYDROGENATED POLYDECENE (1500 CST)</b> (UNII: 4YI0729529) |  |

### Product Characteristics

|                 |       |                     |  |
|-----------------|-------|---------------------|--|
| <b>Color</b>    | white | <b>Score</b>        |  |
| <b>Shape</b>    |       | <b>Size</b>         |  |
| <b>Flavor</b>   |       | <b>Imprint Code</b> |  |
| <b>Contains</b> |       |                     |  |

### Packaging

| # | Item Code        | Package Description                                           | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:72654-033-02 | 125 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/13/2025           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| OTC Monograph Drug | M015                                     | 05/13/2025           |                    |

**Labeler** - Ebanel Laboratories, Inc (079352161)

**Registrant** - Clinical Resolution Laboratory, Inc (825047942)

### Establishment

| Name                                | Address | ID/FEI    | Business Operations    |
|-------------------------------------|---------|-----------|------------------------|
| Clinical Resolution Laboratory, Inc |         | 825047942 | manufacture(72654-033) |

Revised: 5/2025

Ebanel Laboratories, Inc