**NUMB520- lidocaine hydrochloride, phenylephrine hydrochloride spray**
**Clinical Resolution Laboratory, Inc.**

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**Numb520 Spray**

***DRUG FACTS***

***Active Ingredients***

Lidocaine HCL 5%

Phenylephrine HCL, 0.25%

***Purpose***

Local Anesthetic

Vasoconstrictor

***Uses:***

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

***Warnings***

- for external use only.
- avoid contact with the eyes.

**keep out of reach of children.**

**Do not use this product if**

- pregnant or breastfeeding, ask a health professional before use.
- Tamper Evident "Do not use this product" if safety seal is broken or missing.
- you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of prostate gland unless directed by a doctor.

**When using this product**

- do not exceed the recommended daily usage.
- certain persons can develop allergic reactions to ingredients in this product.
- do not put this product into the rectum by using fingers or any medical device or applicator.
- if swallowed, call your Poison Control Center at 1(800) 222-1222.
- if condition worsens or does not improve within 7 days, consult a doctor.

**Stop use and ask a doctor if**

- the symptom being treated does not subside, or redness, irritation, swelling, pain, or other symptoms develop or increase.

### *Directions*

- clean the affected area.
- sensitivity and possible allergy tests advised prior to use. Spray spraingly to affected area after thoroughly cleansing. Wait until anesthetic effect occurs. You may reapply to continue numbing effect.
- apply to the affected area up to 4 times daily.
- children under 12 years of age, consult a doctor.

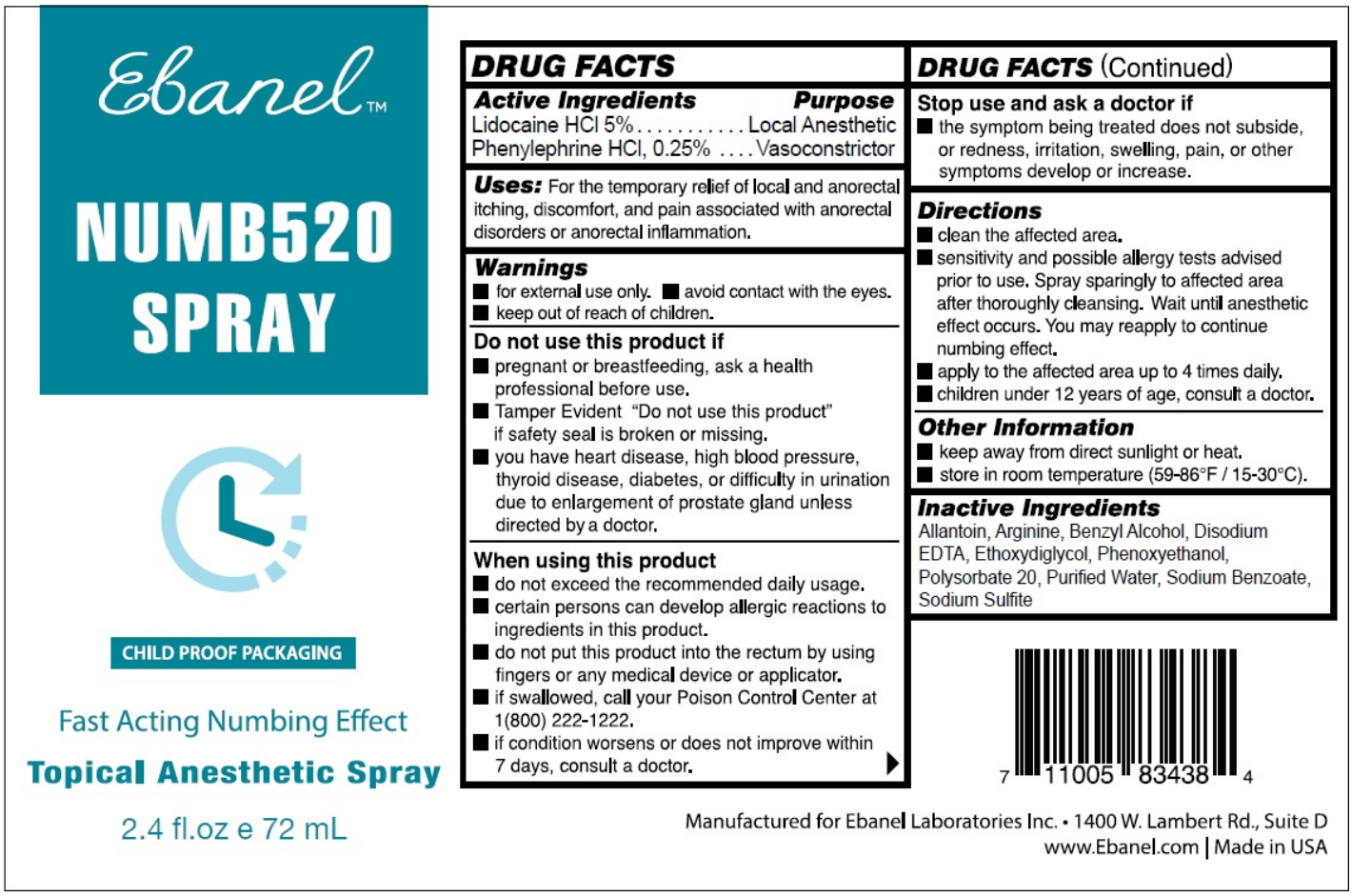
### *Other Information*

- keep away from direct sunlight or heat.
- store in room temperature (59-86°F / 15-30°C).

### *Inactive Ingredients*

Allantoin, Arginine, Benzyl Alcohol, Disodium EDTA, Ethoxydiglycol, Phenoxyethanol, Polysorbate 20, Purified Water, Sodium Benzoate, Sodium Sulfite

**Package Labeling:**




**NUMB520**

lidocaine hydrochloride, phenylephrine hydrochloride spray

## Product Information

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|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:63742-012 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **LIDOCAINE HYDROCHLORIDE** (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 50 mg in 1 mL |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE | 2.5 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ALLANTOIN** (UNII: 344S277G0Z) | |
| **ARGININE** (UNII: 94ZLA3W45F) | |
| **BENZYL ALCOHOL** (UNII: LKG8494WBH) | |
| **EDETATE DISODIUM ANHYDROUS** (UNII: 8NLQ36F6MM) | |
| **DIETHYLENE GLYCOL MONOETHYL ETHER** (UNII: A1A1I8X02B) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **POLYSORBATE 20** (UNII: 7T1F30V5YH) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **SODIUM SULFITE** (UNII: VTK01UQK3G) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:63742-012-00 | 72 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/01/2019 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M015 | 05/01/2019 | |

## Labeler - Clinical Resolution Laboratory, Inc. (825047942)

Revised: 12/2023 Clinical Resolution Laboratory, Inc.