NUMB520- lidocaine cream Clinical Resolution Laboratory, Inc.

Numb520

DRUG FACTS

Active Ingredient

Lidocaine 5%

Purpose

Local Anesthetic

Uses:

for the temporary relief of local and anorectal discomfort associated with anorectal disorders or inflammation.

Warnings

(For external use only)

Do not use

this product if

- pregnant or breastfeeding, ask a health professional before use.
- in case of accidental overdose, get medical help or contact the Poison Control Center immediately.
- seal is broken or missing.

When using this product

- do not exceed the recommended daily dosage unless directed by a doctor.
- certain persons can develop allergic reactions to ingredients in this product.
- do not put this product into the rectum by using finger or any medical device or applicator.

Stop use and ask a doctor if

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

Keep out of reach of children

In case of accidental ingestion, seek medical attention immediately.

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.
- Apply up to 6 times a day.
- Children under 12 years of age: consult a doctor.

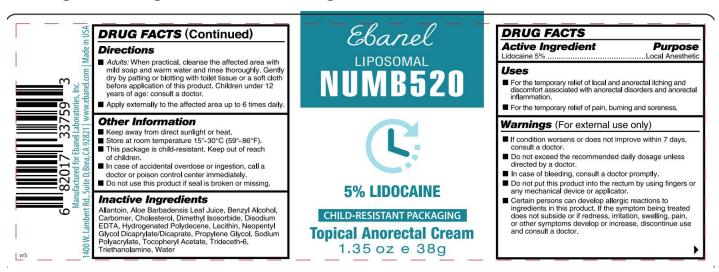
Other Information

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

Inactive Ingredients

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

Package Labeling:63742-033-01 38g



Package Labeling:63742-033-02 125g

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

DRUG FACTS (Continued)

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.
- 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





5% LIDOCAINE

CHILD-RESISTANT PACKAGING

Topical Anorectal Cream

4.4oz e 125g

DRUG FACTS

Active Ingredient

Purpose

aine 5%Local Anesth

Uses

Marketing Start

Marketing End

- 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 detort.

NUMB520

Packaging

lidocaine cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63742-033

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)
LIDOCAINE (UNII: 98PI200987) LIDOCAINE 50 mg in 1 g

Inactive Ingredients Strength **Ingredient Name** ALLANTOIN (UNII: 344S277G0Z) ALOE VERA LEAF (UNII: ZY81Z83H0X) BENZYL ALCOHOL (UNII: LKG8494WBH) CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) CHOLESTEROL (UNII: 97C5T2UQ7J) **DIMETHYL ISOSORBIDE** (UNII: SA6A6V432S) **EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)** NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0KO0R) .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) TRIDECETH-6 (UNII: 3T5PCR2H0C) TROLAMINE (UNII: 903K93S3TK)

#	item code	Раскаде резсприоп	Date	Date
1	NDC:63742-033- 01	1 in 1 BOX	11/01/2021	
1		38 g in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:63742-033- 02	1 in 1 BOX	11/01/2021	
2		125 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M015	11/01/2021			

Labeler - Clinical Resolution Laboratory, Inc. (825047942)

Revised: 5/2025 Clinical Resolution Laboratory, Inc.