NUMB 520- lidocaine cream Clinical Resolution Laboratory, Inc.

DRUG FACTS

Active Ingredients

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

Product label

Manufactured for Ebanel Laboratories, Brea, CA 92821 | 1-844-694-0004 www.ebanel.com | Made in USA

DRUG FACTS (Continued) Directions

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5% LIDOCAINE

CHILD-RESISTANT PACKAGING

Topical Anorectal Cream 4.9 oz e 138.9 g

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NUMB 520

lidocaine cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63742-027

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) LIDOCAINE 5 g in 100 g

Inactive Ingredients

Ingredient Name Strength ALLANTOIN (UNII: 344S277G0Z)

ALOE VERA LEAF JUICE (UNII: RUE8E6T4NB)

BENZYL ALCOHOL (UNII: LKG8494WBH)

CARBOMER (UNII: 0A5MM307FC) CHOLESTEROL (UNII: 97C5T2UQ7J)

DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)

EDETATE DISODIUM (UNII: 7FLD91C86K)

HYDROGENATED POLYDECENE TYPE I (UNII: U333RI6EB7) HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)

NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
.ALPHATOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:63742-027- 01	1 in 1 CARTON	04/07/2025			
1		138.9 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	04/07/2025			

Labeler - Clinical Resolution Laboratory, Inc. (825047942)

Revised: 4/2025 Clinical Resolution Laboratory, Inc.