## NUMB 520- lidocaine cream Ebanel Laboratories, Inc

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## **Active Ingredient Purpose**

Lidocaine 5% ......Local Anesthetic

### **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.

### **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.

### 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.

#### 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

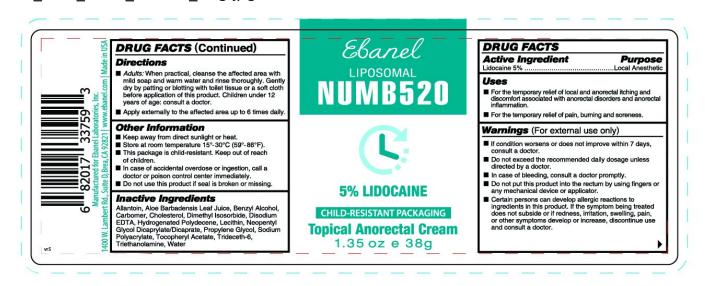
	Pur	pose	Local	Anesth	net
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### **NUMB520**

5% LIDOCAINE
CHILD-RESISTANT PACKAGING
Topical Anorectal Cream
1.35 oz e 38g

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otc label n520 1.35oz 38g.jpg



### **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	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)		
ALLANTOIN (UNII: 344S277G0Z)		
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)		
TROLAMINE (UNII: 903K93S3TK)		

WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics					
Color	white	Score			
Shape		Size			
Flavor		Imprint Code			
Contains					

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:72654- 033-01	38 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2021	

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

# Labeler - Ebanel Laboratories, Inc (079352161)

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

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Clinical Resolution Laboratory, Inc.		825047942	manufacture(72654-033)	

Revised: 5/2025 Ebanel Laboratories, Inc