# NUMB25- 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.

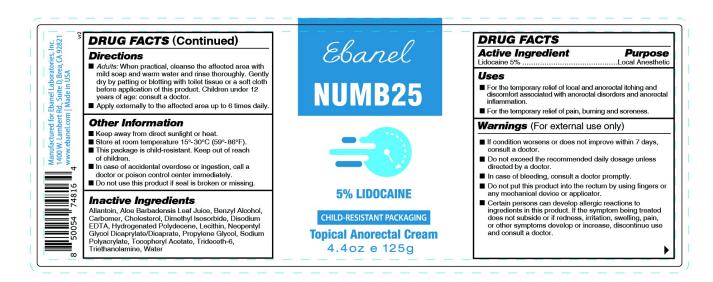
#### Other Information

- 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

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#### NUMB25

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

## NUMB25

lidocaine cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72654-036	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	50 mg in 1 g		

Inactive Ingredients				
Ingredient Name	Strength			
ALOE BARBADENSIS LEAF JUICE (UNII: RUE8E6T4NB)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
TRIDECETH-6 (UNII: 3T5PCR2H0C)				
TRIETHANOLAMINE (UNII: 903K93S3TK)				
HYDROGENATED POLYDECENE (1500 CST) (UNII: 4YI0729529)				
CARBOMER (UNII: 0A5MM307FC)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				

TOCOPHEROL (UNII: R0ZB2556P8)

LECITHIN, SOYBEAN (UNII: 1DI56QDM62)

WATER (UNII: 059QF0KO0R)

CHOLESTEROL (UNII: 97C5T2UQ7J)

DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)

NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)

SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)

EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)

ALLANTOIN (UNII: 344S277G0Z)

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

F	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:72654- 036-02	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	<b>Business Operations</b>	
Clinical Resolution Laboratory, Inc		825047942	manufacture(72654-036)	

Revised: 5/2025 Ebanel Laboratories, Inc.