QUICK NUMB- lidocaine cream
Clinical Resolution Laboratory, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DRUG FACTS

Active Ingredient

Lidocaine 5%

Purpose

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

- 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.

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. Children under 12 years of age: consult a doctor.
- Apply externally to the affected area up to 6 times daily.

Other Information

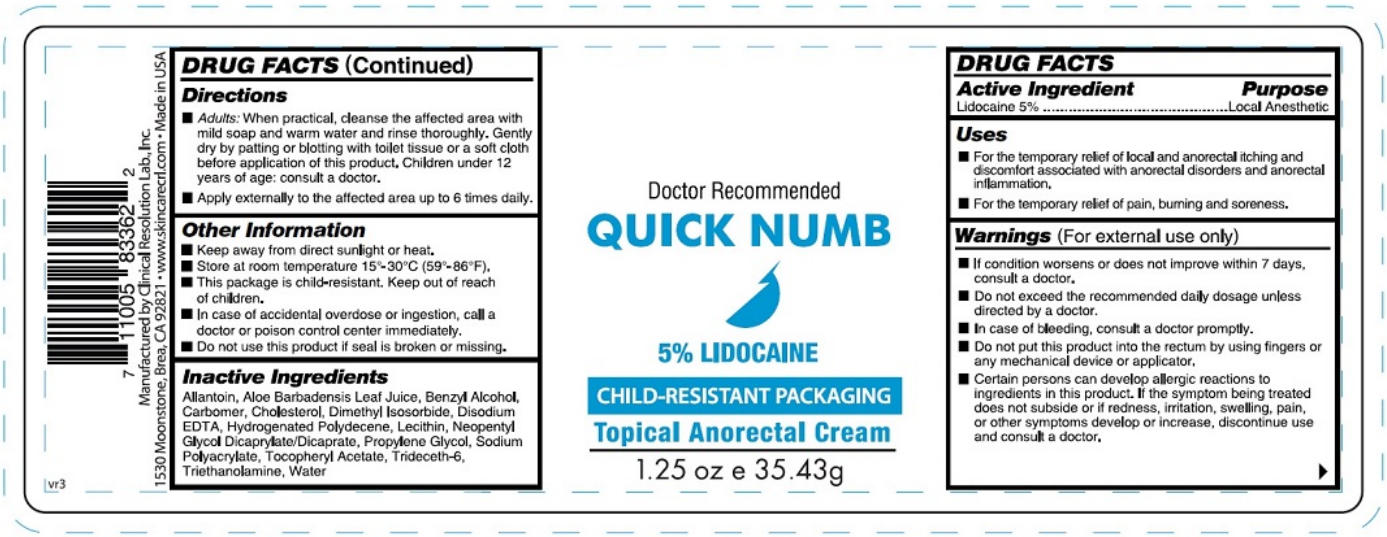
- Keep away from direct sunlight or heat.

- 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

Allanloin, Aloe Barbadensis Leaf Juice, Benzyt Alcohol,Carbomer, Cholesterol, Dlmethyt Isosorbide, DisodiumEDTA, Hydrogenated Polydecene, Lecithin, NeopenlytGlycol Dicaprylale/Dicaprate. Propylene Glycol, Water,Sodium Polyacrytate, Tocopheryt Acetate, Trideceth-6,Triethanolamine

Product label



QUICK NUMB
lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63742-110
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**
ALLANTOIN (UNII: 344S277G0Z)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
HYDROGENATED POLYDECENE (1500 CST) (UNII: 4YI0729529)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63742-110-01	35.43 g in 1 BOTTLE; 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 final	part346	11/01/2021	

Labeler - Clinical Resolution Laboratory, Inc. (825047942)

Establishment

Name	Address	ID/FEI	Business Operations
Clinical Resolution Laboratory, Inc.		825047942	manufacture(63742-110)

Revised: 7/2022 Clinical Resolution Laboratory, Inc.