NUMB 520- lidocaine cream
Clinical Resolution Laboratory, Inc.

Numb 520

DRUG FACTS

Active Ingredient

Lidocaine 5%

Purpose

Local Anesthetic

Uses

For the temporary relief of local and anorectal dicomfort associated with anorectal discomfort or inflammation.

Warnings

(For external use only)

Do not use this product if

- Pregnant or breast-feeding, ask a health professional before use.
- In case of accidental overdose, contact a doctor or Poison Control Center immediately.
- Tamper Evident "Warranty Void...Seal...label atop the container is broken."

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 fingers or any medical device or applicator.

Stop use and ask a doctor if

The symptom being treated does not subside or if redness, irritation, swellinh, 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.

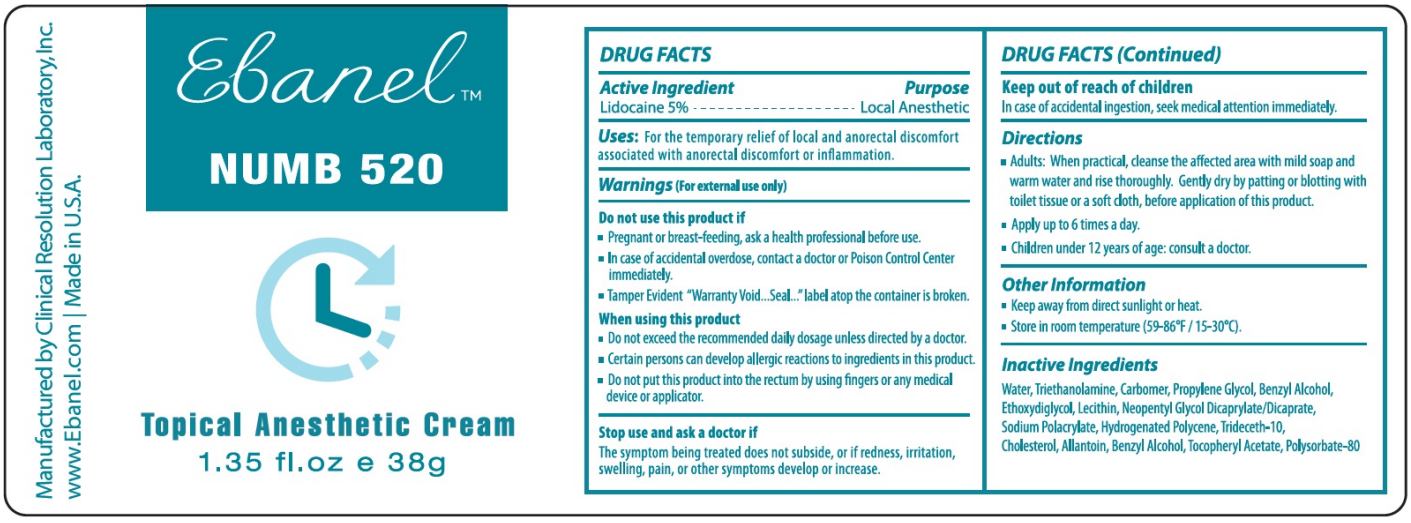
Other Information

- Keep away from direct sunlight or heat
- Store in room temperature (59-860F / 15-300C)

Inactive Ingredients

Water, Triethanolamine, Carbomer, Propylene Glycol, Benzyl Alcohol, Ehtoxydiglycol, Lecithin, Neopentyl Glycol Dicarprylate/Dicarpate, Sodiuym Polyacrylate, Hydrogenated Polydecene, Trideceth-10, Cholesterol, Allantoin, Benzyl Alcohol, Tocopherol Acetate, Polysorbate-80

Package Labeling:



NUMB 520
lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63742-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
TRIDECETH-10 (UNII: G624N6MSBA)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63742-002-01	1 in 1 PACKAGE	12/18/2015	
1		38 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	12/18/2015	

Labeler - Clinical Resolution Laboratory, Inc. (825047942)

Establishment

Name	Address	ID/FEI	Business Operations
Clinical Resolution Laboratory, Inc.		825047942	manufacture(63742-002)

Revised: 12/2023 Clinical Resolution Laboratory, Inc.