NUMB520- lidocaine cream
Clinical Resolution Laboratory, Inc.

Numb520

DRUG FACTS

Active Ingredient

Lidocaine 5%

Purpose

Local Anesthetic

Uses:

for the temporary relief of local and anorectal discomfort associated with anorectal disorders or inflammation.

Warnings

(For external use only)

Do not use

this product if

- pregnant or breastfeeding, ask a health professional before use.
- in case of accidental overdose, get medical help or contact the Poison Control Center immediately.
- seal is broken or missing.

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 finger or any medical device or applicator.

Stop use and ask a doctor if

the symptom being treated does not subside, or if redness, irritation, swelling, 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.

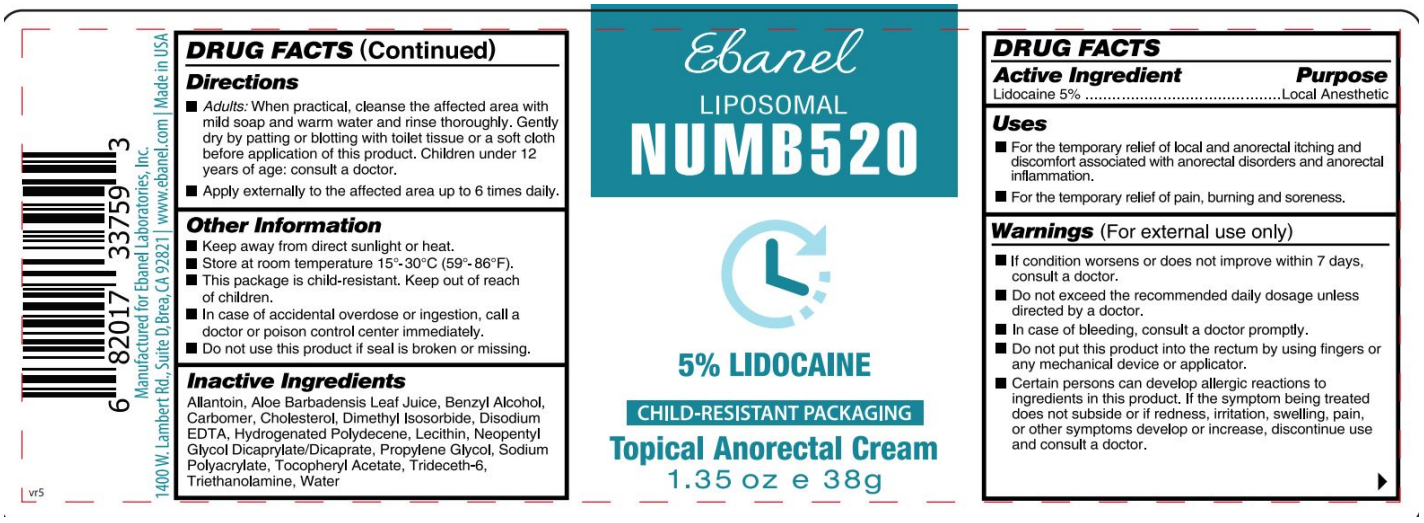
Other Information

- keep away from direct sunlight or heat.
- store at room temperature 15°-30°C (59°-86°F).

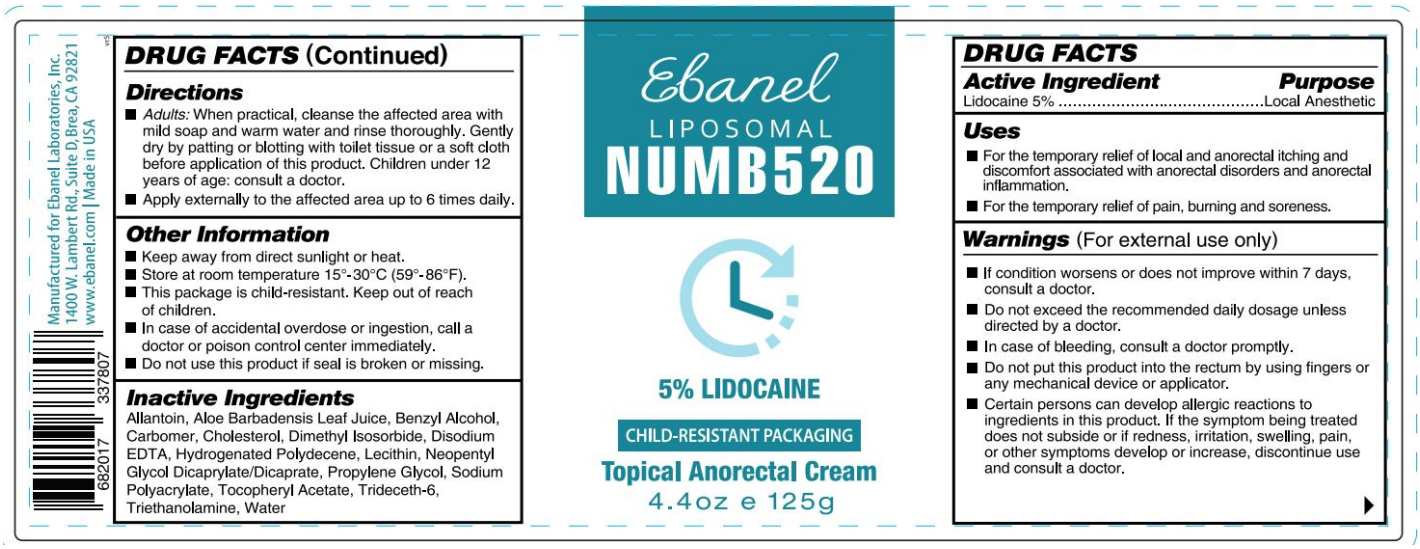
Inactive Ingredients

Allantoin, Aloe Barbadensis Leaf Juice, Benzyl Alcohol, Carbomer, Cholesterol, Dimethyl Isosorbide, Disodium EDTA, Hydrogenated Polydecene, Lecithin, Neopentyl Glycol Dicaprylate/Dicaprate, Propylene Glycol, Water, Sodium Polyacrylate, Tocopheryl Acetate, Trideceth-6, Triethanolamine

Package Labeling:63742-033-01 38g



Package Labeling:63742-033-02 125g



NUMB520

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63742-033
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
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:63742-033-01	1 in 1 BOX	11/01/2021	
1		38 g in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:63742-033-02	1 in 1 BOX	11/01/2021	
2		125 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	11/01/2021	

Labeler - Clinical Resolution Laboratory, Inc. (825047942)

Revised: 5/2025 Clinical Resolution Laboratory, Inc.